Patient Information[1] and Informed Consent Form

A randomised[2], double-blind[3], placebo[4] controlled, parallel group, multi-centre trial in adult subjects with newly diagnosed type 1 diabetes mellitus investigating the effect of Verapamil[5] SR on preservation of beta-cell function (Ver-A-T1D)

Final Version 5 of 11 MAR 2022

Investigational Site:

Sponsor:
Medical University of Graz
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Austria

[1] In order to improve readability, the use of feminine and masculine personal terms is partly omitted in the following text. Both genders are always meant and addressed - if applicable.
[2] Randomisation is a process in which subjects are assigned to different groups using a random mechanism, similar to flipping a coin
[3] Double-blind: study participants and staff do not know which drug combination is administered
[4] A placebo is a drug that contains no active ingredient and therefore cannot cause an effect ("dummy" medicine). Placebos are used as controls in clinical trials.
[5] Verapamil SR belongs to a specific class of drugs that lower blood pressure in patients with high blood pressure.

Administrative information:
EudraCT number: 2020-000435-45
Version: Final 5
Official name of the study: A randomised, double-blind, placebo controlled, parallel group, multi-centre trial in adult subjects with newly diagnosed type 1 diabetes mellitus investigating the effect of Verapamil SR on preservation of beta-cell function (Ver-A-T1D)
Information about the study and the results will be made available at INNODIA network (www.innodia.eu), www.clinicaltrials.gov and potentially in other regional or local registries.

We are inviting you to participate in the clinical trial named above. The clinical trial will be explained in a detailed medical discussion.

Your participation in this clinical trial is voluntary. You can withdraw at any time from the study without giving reasons. If you decide not to participate or if you decide to withdraw from the study at a later stage then this will not have any negative effects on your medical care.

Clinical trials are necessary to discover new treatments for Type 1 Diabetes and other diseases. They also help find new ways to detect, diagnose, and reduce the risk of disease. Clinical trials also show researchers what does or doesn't work in people.
Before you take part in this clinical trial it is important that you receive all the information you need to make an informed decision. Please read carefully the following information leaflet and do not hesitate to speak with the study staff if you have any questions. When you and the study doctor are satisfied, then you will sign a consent form to confirm this. This is called "Informed Consent".

The active study medicine, Verapamil SR is already used to lower blood pressure in patients with hypertension (high blood pressure). It has been used worldwide in adults and children diagnosed with high blood pressure for more than 30 years.

Laboratory research has shown that Verapamil SR can improve the survival of insulin producing beta-cells. Recently, a small clinical trial suggested that Verapamil SR could preserve insulin production in newly diagnosed adults with type 1 diabetes, with patients having fewer low blood sugars.

In this study, we aim to confirm this result by studying more patients, by comparing Verapamil with placebo (dummy medicine) in combination with your normal medicine for diabetes (insulin). Regardless of what you receive in the study, it will not impact on how your normal diabetes medication is working.

This study has been set up within the framework of the INNODIA network.
INNODIA is a global partnership between 26 academic institutions, 4 industrial partners, a small company and 2 patient organisations, bringing knowledge and experience together with one common goal: "To fight type 1 diabetes".

Before you decide if you want to take part in the study, it is important that you understand:

- why the study is being done
- the possible harms and benefits
- what you will have to do if you take part.

Please read the rest of this participant information leaflet. It gives you more information about the study.

What is in this document?

Who to contact

If you have any questions, concerns or complaints about this research study, please feel free to talk to your study doctor *or contact person:*

Study doctor's name: *Doctor's name*
Address: *Doctor's address*
Contact phone number: *Doctor's phone no.*

Other contact person's name: Contact name
Working/hospital address: Contact address
Contact phone number: Contact phone no.

24h Emergency number:

1. Why are we doing this study?

We are doing this study to see if a drug called Verapamil SR can preserve insulin production in patients who have been recently diagnosed with type 1 diabetes. This will be done by comparing Verapamil SR against placebo. You will receive either Verapamil or the Placebo (the dummy drug) by chance (a process called randomisation, similar to flipping a coin) This is explained further below in section 3 "What will you need to do if you take part" and section 4 "What do you need to know about the study medicine?"

What will this study look at?
This study will look mainly at the effect of Verapamil SR on preserving insulin production by the beta cells of your pancreas and the help this gives to your diabetes control.

How many people will take part?
120 subjects are expected to complete the study in Europe and the United Kingdom. .

2. Deciding if you want to take part?

Why are you being asked to take part in the study?
You are being asked to take part because:

- you have recently been diagnosed with type 1 diabetes (T1D)
- you are aged 18 to 44 years old.
- you have no other clinically relevant diseases

What happens if you say 'yes'?
First you need to sign a form saying you agree to take part, this is known as an 'informed consent form'.
This form is at the back of this document.
You will be given a copy of this participant information and the signed form to take home and keep.

What happens if you say 'no'?
You do not have to take part in this study – the decision is yours. If you say "no" this will not affect your current or future medical care.

What happens if you change your mind and no longer want to take part?
If you decide to take part and then change your mind, you can withdraw from the trial at any point without giving a reason. This will not affect your future medical care.
When the study has finished, if you decided to stop taking part at any point during the study, information about you that has already been collected will still be kept. This is required by the national medicine authorities to make sure that the results for the entire study and evidence of side-effects (if any) is not lost..

Taking part in other studies
You cannot participate in this study if you have already participated in another study investigating a drug or treatment in the last 30 days or if you intend to use other investigational drugs during the trial. This is to protect your safety and the conclusions of this study.

3. What will you need to do if you take part?

How do you take the study medicine?
The study medicine is a tablet and should be taken once a day by mouth at approximately the same time.

Your dose of study medicine will be changed over time. You start taking a smaller amount (1 tablet) and then after 4 weeks the dose will be increased to 2 tablets. The dose will be further increased at 8 weeks to 3 tablets, and then you will continue on that same dose for the rest of the study.
It is important that you store and take the study medicines as directed by study staff.

What are your responsibilities?
You must follow all instructions from your study doctor and keep in contact with the study staff during the entire study.
You must remember to return the study medicine (used and unused) at visits specified by study staff and to tell your study staff about any side-effects you might feel.
You have to perform regular blood sugar measurements and do Dried Blood Spot (DBS) tests at home monthly.
You must fill in your diary and take the study medicine.
You are not allowed to consume grapefruit juice, liquorice, St. John's wort, cannabidiol or ginkgo biloba during the whole study period because they can increase the blood levels and effects of **verapamil**

Taking your usual medicines
You need to continue with your usual diabetes treatment and medicines unless the study staff tell you to stop any medications. It is preferred that you continue on the same type of insulin treatment throughout the trial. Tell your study staff if there are changes to your usual medicines during the study or if you start taking a new medicine.

How long does the study last for?
The study lasts approximately 12 months from when you were diagnosed with T1D and started insulin treatment (the date of diagnosis is defined as the date of first insulin injection).
After 12 months, you will be invited to join INNODIA for one final visit at month 24, if you wish to.

What will happen at the different visits in the study?
If you agree to participate in the study and after signing the informed consent form, you will be asked to come in for a screening visit to check if you are eligible for the study, followed by 7 treatment visits at the clinic/hospital and 3 phone calls (phone visits).

It is important that you take part in all of the visits during the study to check on your health and the effect of the study medicines. During the first visit, you will be asked about your health and certain types of personal information (year of birth, gender, ethnicity and race) as well as previous and current medicine(s) and any other relevant medical conditions.
Your study staff will go through your information and let you know if you can take part in the study.

After the first visit a computer-based system will decide by chance which study medication you will receive. This process is called "randomisation".

During the first 12 months, you may be asked to come for extra visits, for example if the study staff consider changing the dose of your study medicines between planned visits, or if you have any side effects that the study staff need to look at.

The amount of time you will spend at the clinic at each visit may vary. This is because the tests and checks will differ at each visit. Talk to your study staff if you want to know more about this.

Summary of tests and information to be collected:

Visit	**Time point**	**Tests and information collected**	**Expected duration**
Visit -1 Screening Visit	0-6 weeks after diagnosis	Demographics (date of birth, gender, ethnicity) Eligibility, informed consent Family and medical history including diabetes care General health and check on any changes to other medication including vaccinations in the last 6 weeks Physical examination including height & weight Electrocardiogram[6], blood pressure, body temperature and pulse Blood, urine & stool samples Pregnancy test (if applicable)	Approximately 2 hours
Visit 0	≤ 2 weeks from V-1, Day 0 for treatment period	Family and medical history including diabetes care General health and check on any changes to other medication including vaccinations in the last 6 weeks Any new health problems Physical examination including height & weight Blood pressure, body temperature and pulse Blood samples Mixed meal tolerance test (MMTT) Continuous Glucose Monitoring (CGM)[7] Diary will be handed out and explained Teaching dried blood spot (DBS) sample technique Pregnancy test (if applicable) Treatment starts	Approximately 5 hours

[6] Measurement of heart activity
[7] Continuous Glucose Monitoring (CGM) is a method to track glucose levels throughout the day and night. CGM systems take glucose measurements at regular intervals, 24 hours a day.

Visit P1, P2 and P3	week1, week 5 and week 9	Phone calls Changes to other medication including vaccinations in the last 6 weeks Any side-effects or new health problems	Approximately 5-10 minutes
Visit V1 and Visit V2	week 4 and week 8	General health and check on any changes to other medication including vaccinations in the last 6 weeks and diabetes care Any side-effects or new health problems Electrocardiogram, blood pressure, body temperature and pulse Blood samples CGM data upload and review of patient diary Pregnancy test (if applicable) Questionnaires to fill in electronically: 1. Hypoglycaemia fear questionnaire (at Visit 1) 2. Diabetes treatment satisfaction questionnaire (at Visit 1)	Approximately 2 hours
Visit V3, Visit V4 and Visit V5	month 3, month 6 and month 9	Update on family medical history General health and check on any changes to other medication including vaccinations in the last 6 weeks and diabetes care Any side-effects or new health problems Physical examination including height & weight Electrocardiogram, blood pressure, body temperature and pulse Blood, urine & stool samples CGM data upload and review of patient diary MMTT. Pregnancy test (if applicable) Questionnaires to fill in electronically: 1. Quality of life questionnaire (at Visit 4) 2. Hypoglycaemia fear questionnaire (at Visit 4) 3. Diabetes treatment satisfaction questionnaire (at Visit 4)	Approximately 5 hours
Visit V6	month 12	Update on family medical history General health and check on any changes to other medication including vaccinations in the last 6 weeks and diabetes care Any side-effects or new health problems Physical examination including height & weight Electrocardiogram, blood pressure, body temperature and pulse Blood, urine & stool samples CGM data upload and review of patient diary MMTT Pregnancy test (if applicable) Optional informed consent for the follow-up visit at month 24 Questionnaires to fill in electronically: 1. Quality of life questionnaire 2. Hypoglycaemia fear questionnaire 3. Diabetes treatment satisfaction questionnaire 4. Diabetes treatment satisfaction questionnaire (changes in current treatment compared to treatment before the start of the study)	Approximately 5 hours

Tests and checks:
During the study, the following tests and checks will be performed:

- Weight, height, blood pressure and pulse, and a general examination.
- If you are a woman and if you are of childbearing potential, you will have to do monthly pregnancy tests (by blood or by urine test at all visits in the clinic , at home between visits and at the last visit if required).
- At most of the clinic visits you will have blood samples taken (also urine and stool samples if needed).
- The blood and urine samples are like those you have when you normally go to the clinic. The collection of the stool sample can be performed by you at home or during the study visit. The study staff will give you instruction on how to collect the sample.
- At each study visit you will have up to 204 mls (up to 14 tablespoonfuls) of blood collected.
- At visit V0 you will be provided with a continuous blood glucose monitoring (CGM) device including a sensor and transmitter and you will be instructed by the site staff how to use the device. You will keep this CGM device for 12 months.
- At 5 visits, a meal test (MMTT) will be done. Please see explanation below.

Diary:
You will also be asked to keep a record of some things in a diary. This includes:
Recording in your diary if you feel unwell or have a low blood sugar ('hypo'). This is so the study staff know when it happened and how you felt.
Recording finger-prick blood glucose values if hypoglycaemic symptoms occur.
Recording your insulin doses 2 weeks before each clinic visit.
Recording hyperglycaemia (high blood blood glucose) levels if you feel unwell
All women of childbearing potential will also need to record the result of a pregnancy test at certain time points.

Mixed meal tolerance test (MMTT):
A MMTT can tell us how much insulin your body is still able to produce (beta cell function). You will be asked to 'fast' (not to eat any food from 12 midnight , but you will still be able to drink water) overnight before the test in the morning. The test will only be performed if your fasting blood glucose (BG) is between 4 and 11.1 mmol/l (72.0 and 199.8 mg/dL). It is possible to correct your blood glucose in the morning to reach the defined blood glucose value. The use of rapid-acting insulin (eg Novorapid, Humalog, Fiasp, or Apidra) is acceptable up to 2 hours before the MMTT and the use of short-acting insulin (e.g Humulin S, Actrapid) up to 6 hours before the MMTT to correct hyperglycaemia (high blood glucose). Basal (long-acting) insulin (eg Lantus, Basaglar, Toujeo, Humulin I, Levemir or Tresiba) can be taken as usual.

The study doctor or nurse will need to insert a cannula (very small, plastic tube) into a vein in your arm at the start of the procedure through which all blood samples will be obtained. We can use a local anaesthetic spray or cream to numb your skin before inserting the intravenous cannula to make it more comfortable for you.

You will then be given a liquid meal which is a drink that is like a milkshake and contains protein, fat and carbohydrate. We will ask you to drink a measured amount of this liquid instead of breakfast. This liquid meal will need to be drunk within 10 minutes. This drink raises BG levels, causing insulin to be released from the beta cells. If you are not able to tolerate this 'liquid meal' you will be advised to eat a standardised breakfast. The standardised breakfast is individually prepared together with a dietician. However, the composition of the standardised breakfast will correspond to the liquid meal for the MMTT. You will be given precise instructions on this from the study staff.

Blood samples will then be taken from the cannula 10 minutes prior to the meal, at the time of ingestion and 15, 30, 60, 90 and 120 minutes after the liquid meal is given, to measure levels of C-peptide (a substance produced in the pancreas at the same time as insulin) and glucose. Food and the bolus dose of short or rapid acting insulin will be given after the test.

Home Mixed meal tolerance test (MMTT) with Dried Blood Spots (DBS):
Between the hospital visits and up until the end of the study we will ask for a tiny sample of your blood to be collected every 4 weeks by finger prick at home. We call these samples 'dried blood spots' (DBS). DBS samples are a new and convenient way of measuring C-peptide and we will give you written instructions and teach you how to do this at your first visit.
You can use the same technique to prick your finger as you use to test your glucose level. However, we will ask you to drop a spot of your blood on to some circles that will be marked on the white sample card. The DBS samples will need to be taken before breakfast and 60 minutes after eating breakfast.

For the days when you take your DBS samples, we will supply a 'liquid meal' which is described in the MMTT section. This is a home MMTT, a shorter version of the MMTT that is performed at the clinic. Knowing the exact nutritional content of what you have for breakfast will help the doctors analyse the C-peptide results. If you are not able to tolerate this 'liquid meal' at all, you will be advised to eat a standardised breakfast.

Taking DBS samples will let us see what happens to your C-peptide levels, in your blood over time. We will ask that you record your BG readings at the same time you take your DBS samples on a form. This form and sample card will need to be returned to the study team by post using a prepaid envelope each time a sample is taken. Detailed instructions will be given to you by the study team.

4. What do you need to know about the study medicine?

In this study there are 2 study medicines:

- Verapamil SR (the active medicine being tested)
- Placebo (a dummy medicine that looks like the study medicine but has no effect on the body).

Verapamil SR will be taken as 120 mg (one tablet) for the first 4 weeks, increased to 240 mg (2 tablets) for the next 4 weeks and thereafter 360 mg (3 tablets) until month 12. For participants on placebo, the number of tablets will increase in the same way.
The reason patients on placebo take the medication in the same way is to maintain blinding, but the reason for having placebo is so that there is a comparison group to see whether the treatment works in the active group.
It is important that you and study staff do not know which study medicine you are taking as it might affect the results of the study.

Throughout the entire study you will only take either the study medicine Verapamil SR or the placebo.

Which study medicine will you get?
The study medicine you get is decided by chance by a computer programme - like flipping a coin. This is called randomisation. You will have a 1 in 3 chance of receiving a placebo (dummy drug) and 2 in 3 chance of receiving the active medication. You and your study team will not know which of the study medicines you will get. However, if your safety is at risk, your study staff will be told in order to decide your future treatment.

What if I miss a dose of study medicine?
If you forget to take a dose of your study medication and you remember on the day it should be taken, then take it when you remember.
If you forget to take your study medication and remember the day after it should have been taken, then DO NOT take two doses on that day. You should skip the missed dose altogether and make a note of the date of the skipped dose. Tell your study nurse or doctor at your next clinic visit.

About Verapamil SR
Verapamil SR is a tablet that is used to lower blood pressure in patients with hypertension (high blood pressure). Verapamil has been prescribed by doctors for over 30 years. The SR stands for sustained-release and enables a slow release of the drug in the body over an extended period of time.

5. What are the possible side effects or harms of taking part?

Your study staff will watch closely for possible health problems that happen in relation to you taking part in the study. As with all medicines, side effects may happen.
If side effects happen, they will be treated if needed. You may be asked for an extra blood sample or clinical test if you have any side effects that the study staff needs to look at.
Tell your study staff about any side effects or health problems you have while taking part in the study. Tell the doctor or staff even if you do not think that the side effects were caused by the study medicine.

Side effects of study tests and checks:
Blood sampling
During this study, small amounts of your blood will be taken. This allows the study staff to see how you are doing and if or how the study medicine works. You may feel a little discomfort,

bruising, bleeding or swelling where the needle goes in. There is also a very small risk of infection where the needle goes in.

ECG
When making a recording of the electrical activity of your heart by an electrocardiogram (ECG), your skin may react to the sticky electrode patches. Any skin irritation usually disappears when the patches are removed.

Side effects of Verapamil SR
Since verapamil has been used for many years, the possible side effects are well known. The most common side effects (occuring in more than 1 in 10 patients) of Verapamil SR include constipation, dizziness, nausea, low heart rate, low blood pressure, hot flush or peripheral oedema (Your body may keep more water than it should. This causes swelling around your ankles and other joints.), headache and fatigue (occuring in 1in 10 to 1 in 100 patients; weariness and tiredness).
Other more uncommon side effects include: arrhythmic disorder, (your heartbeats too quickly, too slowly, or with an irregular pattern)
Very rare side effects (occuring in less than 1 in 10,000 patients) include elevated liver enzymes (liver problems) and shortness of breath (due to heart failure).
Driving and other activities. In some people, their ability to drive, operate machinery or work in situations without secure support may be affected by Verapamil. This applies to a greater extent at the start of treatment, when the dose is increased as well as in combination with alcohol. Verapamil may possibly increase blood alcohol levels and slow down its elimination, thereby potentiating the effects of alcohol. If you think the medication has affected your ability to concentrate, please avoid driving and other activities that require good concentration and contact your study team.
Low blood pressure (hypotension)
Low blood pressure does not always cause symptoms, but you may need treatment if it does. Symptoms of low blood pressure can include: light-headedness or dizziness, feeling sick, blurred vision, generally feeling weak, confusion or fainting.
If you feel hypotensive you should take Verapamil SR in the evening before you sleep.

Pregnancy information for women and men
Women
Do not take part in this study if you are pregnant, breast-feeding or planning to become pregnant during the next 12 months. This is because we do not know how the study medicine may affect you or your baby. If you take part in the study and if you are a woman of childbearing potential, you and your male partner must use highly effective birth control. Your study staff will give you advice about types of birth control that work the best before the study starts.
At the beginning of the study, every month and while taking the study treatment , all women who are of childbearing potential will have a pregnancy test.
If you take part and think you may have become pregnant, tell the study staff straight away and stop taking the study medicine. However, information about you, your pregnancy and your baby will still be collected. This is so that we can watch for anything unusual.

Men

Study staff will give you advice about adequate contraception during the study period.
Men will be required to use adequate contraception for the entire duration of the study and for 7 days after the last dose of study medication. This is because we do not know how the study medicine may affect the development of a baby conceived by a partner of a trial participant.

6. What might the benefits be to you?

You may not directly benefit from taking part in this study but the information collected as part of your participation in this study may benefit patients with T1D in the future. You may benefit from having tests, checks and general talks with your study doctor.

You will not have to pay for the study medicine and the CGM while you are participating in the study.

7. Who is involved and more information about taking part

Who is paying for this study?
The trial is sponsored by the Medical University of Graz, Austria.
This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 115797 (INNODIA). This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and European Federation of Pharmaceutical Industries and Associations (EFPIA), Juvenile Diabetes Research Foundation (JDRF) and The Leona M. and Harry B. Helmsley Charitable Trust.

Will you receive any payments? Participants or their legal representatives of this study will not receive any payment for participating in this study, however, all reasonable travel costs incurred whilst travelling to the clinical centre for each study visit will be reimbursed to the participant or legal representative by the coordinating centre.

Who has reviewed and approved this study?
This study, the patient information and informed consent, has received a positive opinion from an independent committee called an Ethics Committee/Institutional Review Board. In addition, approval to perform this study has been granted by the National Medicines Authority of your country.

How have patients and the public been involved in this study?
This study, the patient information and informed consent, has been reviewed by the INNODIA Patient Advisory Committee (PAC) that includes members of the public involved with patient and public engagement with research.

What if you decide to stop taking the study medicine or stop taking part in the study?
If you consider to stop taking your study medicine or stop taking part in the study, please talk to your study staff before making any changes. This is to make sure the study medicine is stopped in a safe way. Even if you permanently stop taking your study medicine, it is helpful if you still have the study check ups to see how it has affected you.

What if the study staff decide to stop the study medicine?
The study staff may stop you from taking the study medicine at any time - even if you want to carry on. Some reasons may include: for your safety - for example if your body has a bad reaction to the study medicine, if the study medicine is not the best choice for you, if your illness becomes worse, if you are a woman and you become pregnant or would like to become pregnant.

What happens to your blood samples?
The INNODIA network brings together diabetes experts from across Europe and your samples will contribute to many studies into the causes of diabetes.
Your samples will only be identified by your unique study number. Some samples will be stored and analysed at the end of the study whereas others will be sent immediately to laboratories across Europe and the UK. Safety bloods will be analysed locally at your study site, to check that the drug is acting in a safe way.
One of the blood samples you donate will be used for genetic research by extracting the DNA from white blood cells and studying the genes that you have inherited from your parents. We will not provide the results of this genetic research to you or your doctors since we are not looking for specific genetic diseases but only genes associated with diabetes and its complications.
The white cells will also be used to study the body's immune responses and other blood samples will enable the measurement of diabetes related auto antibodies[8] and to discover new markers of disease progression. The urine samples may also provide new markers and the microorganisms in the stools may provide insights into disease mechanisms.
At the end of the study, DNA samples and some blood samples will be stored in a central Biobank and will be made available for investigators at other centres. All data and biological samples will be labelled with a unique centre and participant ID number. Only your local research team will be able to identify who provided the samples. Samples sent to laboratories will be anonymised.
The results of the MMTTs and the DBS samples will be used to understand how beta cell function changes over time.

Storage of your samples for future research studies
We would like to use your samples to contribute towards many other research studies into diabetes as part of the wider INNODIA research group. These future research studies are optional and will receive a positive opinion from the relevant ethics committee. If you agree to this, you can give your consent on page 19 "Informed consent".

What if the company paying for the study or the authorities decide to stop the study?
Study staff/INNODIA, the national medicine authority or the Research Ethics Committee may end the study early at any time - for safety or if there is another good reason to do so. If this happens, you will be told by your study staff.

[8]Antibodies are cells produced by the immune system and directed against the body's own healthy tissue

8. **How will my personal data and samples be used?**

We will need to use information from you, your medical records and your GP for this research project. This information will include your NHS number, name, age, gender and contact details. People will use this information to do the research or to check your records to make sure the research is being done properly such as study staff and consultants, auditors, research organisations or laboratories working for the Medical University of Graz, the Research Ethics Committee and national medicine authorities from other countries People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Some of your information will be sent to countries outside of the UK. They must follow our rules about keeping your information safe. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

All persons who receive access to your encrypted (coded in a way to protect it) and non-encrypted data are subject to the UK Data Protection Act in its current version and to the General Data Protection Regulation (GDPR) when dealing with the data.

The transfer of pseudonymous data to countries outside the EU (non-member states) is planned as part of this clinical study - these countries are not subject to the GDPR. Not all non-member states have suitable arrangements in place to ensure an equivalent level of data protection as exists in EU countries that are subject to the GDPR. As such, there is the risk that you will not be able to enforce the rights to which you are entitled under the GDPR. However, the recipient of the data is obliged to protect your data appropriately. By participating in this clinical study, you are consenting to your data being transferred to non-member states.

Your consent forms the legal basis for the processing of your personal data.

The duration of the storage of your data beyond the duration on the trial is also regulated by law.

Your encrypted glucose data from the sensor is stored in a Cloud based solution (Dexcom Clarity), an officially approved data storage and data preparation solution, where it remains available even after the study is completed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information by:

- Visiting: www.hra.nhs.uk/information-about-patients/
- Visiting: www.hra.nhs.uk/patientdataandresearch
- asking one of the research team

- sending an email to: datenschutz@medunigraz.at

You also have the right to file a complaint with the UK Data Protection Authority regarding the handling of your data on 03031 231113 or https://ico.org.uk/global/contact-us/

OR you can contact the persons responsible for Data protection at the study centre: Data Protection Officer at the [*enter site name*] [*enter e-mail contact]*

Future use of your sample(s) collected during the study

Your study samples will only include your code number and, if appropriate, your gender and age. Your samples will be used for research related to the causes and treatment of Type 1 diabetes. If you have any questions you may contact the data protection officer (DPO) for further information about the management of your study samples, via datenschutz@medunigraz.at

Your samples may also be shared with research partners in Europe and with other countries in the world for testing and analysing for scientific research purposes. Before sharing with research partners, your samples will be labelled with a code number that is different from your study number. Research partners working with the Sponsor are not allowed to share samples with anyone who is not authorised by the Sponsor.

You will not be paid for any use of your samples, results, or inventions made from research on them. By signing the attached consent form you are providing your consent for your samples to be used by the Sponsor. The Sponsor (and research partners) plan to own the use of the results, treatments, or inventions that can be made from this research. If you withdraw your consent to take part in the study, you may contact the study doctor and have those of your samples that have not yet been used destroyed. The results obtained from your samples before you withdraw your consent remain the property of the study Sponsor.

Insurance

Any participation in a clinical study involves risk; however small it is. Even if there is no fault, the Sponsor accepts responsibility for damage caused to the participant (or in the event of death, his/her dependents) and directly or indirectly linked to his/her participation in the study.

We will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). We will pay compensation where the injury probably resulted from:

- A drug being tested or administered as part of the trial protocol;
- Any test or procedure you received as part of the trial.

Any payment would be without legal commitment. (Please ask if you wish for more information on this). We would not be bound by these guidelines to pay compensation where the injury

resulted from a drug or procedure outside the trial protocol or where the protocol wasn't followed.

The Sponsor has taken out insurance for this responsibility. The insurer is Newline Europe Versicherung AG, under policy number: SYD20982393A
You are asked to report any new health problem to the study doctor before consulting another doctor, taking any other medication or receiving any other medical treatment. If for any reason, you consult another doctor during this study, you must inform him/her that you are taking part in a clinical study and show them your patient card. This could be important in treating your symptoms.

In the event of disagreement either with the study doctor or with the expert appointed by the insurance company and also whenever you feel it is appropriate, you or - in case of death - your dependents, may bring proceedings against the insurer directly by contacting Newline Europe Versicherung AG Schanzenstraße 28a, 51063 Köln, telephone number +49 221 9669 4510

9. Who can you talk to for more information?

If you have any questions, concerns or complaints about this research study, please feel free to talk to your study staff. Their contact information can be found on the first page of this document or for independent advice you may contact: Dr Justyna K Witczak, Consultant in Diabetes&Endocrinology, MD(PUMS), MD (CU), MRCP(UK)
Tel: 02920742341, email: justyna.witczak@wales.nhs.uk

This includes if you feel you have been harmed as a direct result of taking part in the study.

In addition, as required by law, as long as it does not impair the conduct of the clinical trial, you have the right to view the data collected on you and the possibility of correcting it if you find any errors.

10. Information related to the Coronavirus infection (COVID-19) outbreak

According to the current state of knowledge, there is no increased risk of COVID-19 disease through the intake of Verapamil SR.

As we always want to ensure the safety of patients and their families, additional measures may be taken during the trial that could affect your well-being. Possible measures may include

- Taking your body temperature when you come into the clinic.
- An additional examination of symptoms each time you arrive at the clinic (for example, questions about coughing, shortness of breath, fever, etc.).

Thank you for taking the time to read this participant information. If you have decided to take part, please fill in the 'Informed Consent form' on the next pages after conversation with the study staff seeking informed consent.

11. Informed Consent Form

By signing this form, I agree with all the following statements:

Taking part		***Circle relevant box***		***Initials***
1	I have been given verbal and written information about this study.	Y	N	
2	I have read and understood the information given to me.	Y	N	
3	I have had enough time to think about taking part.	Y	N	
4	I have had the chance to ask questions - and all my questions have been answered.	Y	N	
5	I understand that I do not have to take part and that I am free at any time to stop taking part. Also, that I do not have to give a reason and that this will not affect my future treatment.	Y	N	
6	I understand that one of the blood samples I donate will have DNA extracted from it to study the genes associated with diabetes and its complications. The results of these test will not be made available to me or my doctor. The DNA samples will be stored at the end of the study and made available for investigators at other centres. Blood samples will be labelled with a unique centre and participant ID number. Only my local research team will be able to identify who provided the samples. Samples sent to laboratories will be anonymised.	Y	N	
Information about me I understand the following points:				
7	A number of people can see my personal medical file. This is to make sure that the study is done correctly and that all information is recorded correctly. All personal details will be treated as strictly confidential by all of these people. The people who can see my records are:	Y	N	

	• *[enter site name]* staff and consultants, auditors, research organisations or laboratories working for the *[enter site name]* • Research Ethics Committee/Institutional Review Board and national medicine authorities.			
8	All information collected during the study is stored electronically in a database and may be shared with other researchers who are not working on this study. The information can also be sent to other countries in the world. The information will never have my name on it.	Y	N	
9	If I decide to stop taking part during the study, information already collected cannot be deleted. This is required by the national medicine authorities to make sure that the results for the entire study can still be used.	Y	N	
10	The results of this study may be made publicly available.	Y	N	
11	I accept that the study staff may get information related to the study from people like my family doctor. They may also look at publicly available information.	Y	N	
12	I agree that my samples can be used for future research studies	Y	N	
About this form				
13	I will get a copy of this information and this signed and dated form.	Y	N	
14	I agree to take part in this research study.	Y	N	

To be completed by you I agree with all of the statements on this form and would like to take part in the study: Signed: Date:
Name (print):

To be completed by the study doctor seeking the informed consent (to be signed by the study doctor or appropriately medically qualified designee) By signing this form, I confirm that the entire informed consent process has been conducted before any study procedures have taken place: Signed: Date:
Name (print):