

Key:
■ Stopping rules apply
■ Extra visits for LIRA 3mg group only
■ End of study

Appendix 3.

Table 1. Outcome measures and planned visits during the enrolment and control visits.

WEEKS	-6 to -1/52	0/52	2/52	4/52	8/52	12 /52	16 /52	20 /52	32 /52	40 /52	52 /52	65 /52*	78 /52	91 /52*	104/52
VISIT WINDOW	Screening ^{aa}	Base-line	+/- 3dys	+/- 3dys	+/- 7dys	+/- 7dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys
Visit No.	1	2	3	4	5	6	7	8	9	10	11	12*	13*/12	14*	15*/13
STUDY PROCEDURES															
Inclusion/exclusion criteria	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Informed consent	X														
Randomisation		X													
Injection training*		X													
Titration/ Review Visit* (dose*) /or telephone call) ^{ss}		X 1.2 ^{ss} 0.6 ^{\$}	X 2.4 ^{ss} 1.8 ^{\$}	X 3.0 ^{\$}											
Other HCP	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Glucose self-monitoring training/ education		X													
Dispensing (or unsched visit) ^{###}		X	X	X	X	X	X	X	X	X	X	X	X	X	X
DATA COLLECTION															
Subject demography	X														
Medical/Surgical history	X														
Medication history	X														
Concomitant medication	X														
Changes in med/diseases		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Height	X														
BMI	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Waist Circumference	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Blood Pressure	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Pulse rate	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Liver function tests	X								X		X				X
Renal function tests	X								X		X				X
Thyroid function tests	X								X		X				X
Haematology profile	X								X		X				X
Lipids	X								X		X				X
HbA1C	X								X		X				X
Amylase	X								X*		X*				X*

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VISIT WINDOW	Screening**	Base-line	+/- 3dys	+/- 3dys	+/- 7dys	+/- 7dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys	+/- 14dys
Visit No.	1	2	3	4	5	6	7	8	9	10	11	12*	13* /12	14*	15* /13
King's Obesity Staging System	X										X				X
Epworth score	X										X				X
Stop Bang Questionnaire	X										X				X
Sleep Study (home based ambulatory sleep monitor)**	X										X				X
Apnoea Hypopnoea Index**	X										X				X
Oxygen desaturation index**	X										X				X
CPAP pressures**	X										X				X
Pregnancy test	X	X	X*	X*	X*	X*	X*	X*	X*	X*	X	X*	X*	X*	X
ACR***	X								X		X				X
AE/SAE recording		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Adherence with injection*			X	X	X	X	X	X	X	X	X	X	X	X	X
Adherence with other anti-obesity medications#							X		X		X				X
Adherence to Specialist Weight Management Service (SWMS)			X	X	X	X	X	X	X	X	X	X	X	X	X
Contacts with GP/HCP		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Inpatient and Outpatient apt's		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Medications cost		X									X				X
QUESTIONNAIRES															
HSRUQ		X									X				X
TSQM###		X									X				X
EQ-5D		X									X				X
IWQOL-Lite		X									X				X
IPAQ-Long		X									X				X
PHQ-9		X									X				X

*Only for participants at the LIRA 3mg group who are on active treatment

§Titrated dose participant will leave on at the end of the visit. ^{§§}Optional Telephone calls to check tolerance and up-titrate at weeks 1, 3 & 5.

**As required for participants with identified risk OSA or current OSA based on CPAP use and type of CPAP (variable or fixed pressures CPAP)

*** Only for prediabetic, diabetic and hypertensive individuals

Only for participants in the standard care group on treatment with anti-obesity drugs

###Only for participants with diagnosis of T2DM

For participants on treatment either with LIRA 3mg or other anti-obesity medication

^ Only participants who report problems with injection and/or side-effects may be reviewed by study clinician

^^ A repeat screening visit may take place to assess eligibility

Drug dispensing unscheduled visits may occur at any point within the study period for participants in LIRA3 mg group as required (not depicted above)