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Lateral episiotomy versus no episiotomy to reduce obstetric anal sphincter injury in vacuum-assisted delivery in nulliparous women: study protocol on a randomised controlled trial

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ABSTRACT

Introduction Obstetric anal sphincter injury (OASIS) occurs in 5%–7% of normal deliveries and increases with vacuum extraction (VE) to 12%–14% in nulliparous women in Sweden. Lateral/mediolateral episiotomy may reduce the prevalence of OASIS at VE in nulliparous women. The current use of episiotomy is restrictive. The protective effect and consequences are uncertain. This trial will investigate if lateral episiotomy can reduce the prevalence of OASIS and assess short-term and long-term effects.

Methods and analysis This is a multicentre randomised controlled trial of lateral episiotomy versus no episiotomy in nulliparous women with a singleton, live fetus, after gestational week 34+0 with indication for VE. A lateral episiotomy of 4 cm is cut at crowning, 1–3 cm from the midline, at a 60° angle. The primary outcome is OASIS by clinical diagnosis analysed according to intention to treat. To demonstrate a 50% reduction in OASIS prevalence (from 12.4% to 6.2%), 710 women will be randomised at a 1:1 ratio. Secondary outcomes are pain, blood loss, other perineal injuries, perineal complications, Apgar score, cord pH and neonatal complications. Web-based questionnaires at baseline, 2 months, 1 and 5 years will be used to assess pain, incontinence, prolapse, sexual function, quality of life and childbirth experience. A subset of women will receive follow-up by pelvic floor sonography and pelvic examination. Mode of delivery and recurrence of OASIS/episiotomy in subsequent pregnancies will be assessed at 5 and 10 years using register data.

Ethics and dissemination The trial is open for enrolment. The trial has received ethical approval from the Regional Ethical Review Board of Stockholm and full funding from the Swedish Research Council. Women are interested in participation. The predominant restrictive view on episiotomy may limit recruitment. Results are of global interest and will be disseminated in peer-reviewed journals and at international congresses.

Trial registration number NCT02643108; Pre-results.

Strengths and limitations of this study

- The main strength is the randomised trial design, which will provide evidence for routine or restrictive lateral episiotomy at vacuum extraction in nulliparous women.
- Another strength is the setting with relatively high obstetric anal sphincter injury (OASIS) rates and low episiotomy rates, enabling a realistic sample size.
- One limitation is that the primary outcome, diagnosis of OASIS, is made by clinical examination, which may limit diagnostic accuracy.
- Another limitation is the restrictive view on episiotomy, which may hamper trial feasibility.

BACKGROUND

Obstetric anal sphincter injury (OASIS) is a serious complication to vaginal delivery. It is the most important cause of female anal incontinence, and therefore important to avoid.[1] OASIS occurs in 5%–7% of spontaneous vaginal births and increases with operative vaginal delivery to 12%–14% in nulliparous women in Sweden.[2–4] In 2017, approximately 10% (6%–17%) of nulliparous women were delivered by vacuum extraction (VE) depending on delivery site, and only a negligible number were delivered by forceps.[4]

The use of episiotomy in Sweden is restrictive and was reported in approximately 10% of all vaginal deliveries and 30% of VE in 2017, with large regional variation (10%–79%).[4] The restrictive use of episiotomy spread in the 1990s, especially after Swedish publications reported little protective effect on severe perineal injury and increased early postpartum pain compared with spontaneous tears.[5–7] The inability to reduce OASIS in normal delivery has been

confirmed in repeated Cochrane meta-analyses and restrictive use is now generally recommended.[8 9] The restrictive approach has also influenced practice at operative vaginal delivery, supported by the uncertain effect of episiotomy in VE in the Swedish setting.[10] Following decades of restrictive use, midwives and doctors may have lost knowledge in correctly performing and repairing episiotomies. There is an inverse correlation between a nation's rate of episiotomy and rate of OASIS, and the optimal rate of episiotomy in operative vaginal delivery is not known.[11]

Several recent retrospective register studies have shown that nulliparous women who received a lateral or mediolateral episiotomy at VE had a reduced prevalence of OASIS compared with women without episiotomy.[12–15] Lund *et al* compiled the outcome of 15 register studies in a meta-analysis published in 2016, and concluded that a mediolateral or lateral episiotomy significantly reduced the risk of OASIS at VE in nulliparous women with an adjusted OR (aOR) of 0.53 (95% CI 0.37 to 0.77).[16] Numbers needed to treat was 18.3 (95% CI 17.7 to 18.9). The protective effect of mediolateral or lateral episiotomy seemed most pronounced when performed in more than 75% of VE with aOR 0.37 (95% CI 0.15 to 0.92). The results from these studies were so promising that an official Swedish guideline and a new national educational programme launched in 2017 advocated to consider a mediolateral episiotomy at operative vaginal deliveries in nulliparous women.[17 18]

In register studies, despite controlling for several confounding factors, there is a risk of selection bias, registering shortcomings and confounding by indication. Furthermore, non-measured variables, such as operator skills and tissue properties, might result in residual confounding. None of the register studies showing a protective effect of lateral/mediolateral episiotomy have adjusted for tissue properties or taken the operator's experience or track record of OASIS into account. Such factors may be balanced in a randomised controlled trial (RCT). Hence, several authors and institutions, including the Cochrane Collaboration and the Database of Uncertainties about the Effects of Treatments/National Institute for Health and Care Excellence Evidence Search, state that the protective effect of a lateral/mediolateral episiotomy at operative vaginal delivery should be investigated in an adequately sized RCT.[9 16 19–21]

There is one published British pilot RCT on routine versus restrictive use of episiotomy (undefined type) in operative vaginal delivery in 200 nulliparous women, but the trial was underpowered mainly due to a fairly high rate of episiotomy (52%) in the restrictive group and moderate prevalence of OASIS in both groups (routine 8.1% vs restrictive 10.9%).[22] The authors estimated that a sample size of 1600 women would have been necessary to determine a difference at that level. Ethical concerns arise when a number of women will sustain an iatrogenic perineal injury to perhaps avoid OASIS, which may heal well after adequate suturing. Yet, only 4% of the women in the restrictive group in the British pilot trial had an intact perineum after operative vaginal delivery.

Many earlier studies on the effects of episiotomy do not specify the type, although mediolateral episiotomies are preferred in Europe, while lateral episiotomies are mainly used in Finland.[11 22 23] It is evident that mediolateral and lateral episiotomies often are confused both in clinical practice and in research.[16 24 25] As surveyed at a Nordic Congress of Obstetrics and Gynaecology, the majority of Nordic obstetricians declared to perform a lateral episiotomy, but 64% called it a mediolateral episiotomy.[24] Only 20% performed a typical mediolateral episiotomy and one-third drew an unclassifiable type. In an effort to standardise terminology, Kalis *et al* stated that a lateral episiotomy 'begins in the vaginal introitus 1 or 2 cm lateral to the midline and directed downwards towards the ischial tuberosity', while a mediolateral episiotomy is more unclear with a suggested definition starting within 3 mm of the midline and directed laterally at an angle of at least 60° from the midline.[26] In The Effect of Episiotomy on Advanced Perineal Tears and Other Maternal and Fetal Outcomes Randomized Controlled Multicentric Trial (EPITRIAL), Sagi-Dain *et al* use 'lateral/mediolateral' episiotomy, defined as an incision at 45°–60° and 3–4 cm long.[25]

We have decided to use lateral episiotomy in our RCT, defined further in the methods section. The purpose of the lateral episiotomy is to cut the bulbocavernosus muscle, which is thought to constitute the main restraining tissue in the vaginal opening at crowning. Lateral episiotomy may affect the superficial transverse perineal muscle, but ideally not the levator muscle, perineal body or margins of the external anal sphincter muscle, which may be a risk at a mediolateral episiotomy with an insufficient angle, distance from the midline and length.[27–31] Furthermore, current evidence suggests little difference between the techniques regarding bleeding, postpartum perineal pain and sexual resumption.[32–35] A correlation between the extent of tissue damage and degree of pain has been observed, but conflicting observations on pelvic floor function and pain after any episiotomy versus spontaneous perineal injury call for a long-term follow-up to assess the optimal treatment at delivery.[32 36–38]

In all, to our knowledge, there is no published adequately sized RCT to assess the protective effect of lateral episiotomy at VE in nulliparous women, nor sufficient published data on long-term postpartum complications from episiotomy versus spontaneous perineal injury at VE.

METHODS AND ANALYSIS

Aim

The aim of this RCT is to investigate if routine lateral episiotomy can reduce the incidence of OASIS at VE in nulliparous women, compared with a no episiotomy policy, and to assess short, medium and long-term effects

on pelvic floor symptoms with the two different episiotomy strategies.

Study design and treatment allocation

We used the Standard Protocol Items: Recommendations for Interventional Trials checklist when writing our report (online supplementary appendix 1).[39 40] Randomisation is performed on a 1:1 basis, based on computer-generated random permuted blocks provided by the independent, non-profit Karolinska Trial Alliance. Treatment group is allocated using sealed opaque envelopes placed on the VE equipment cart for immediate and easy access. When the decision to perform a VE has been made by the attending physician and the patient's consent has been verified, the envelope is opened by the assistant nurse or midwife. The allocated treatment is confirmed by the attending physician, the midwife and the woman in labour. The allocated treatment cannot be blinded to women or investigators in the trial, nor at follow-up, due to the design of intervention/no intervention. During analysis, group allocation will be open to the investigators, to enable both intention-to-treat and per-protocol analysis. The complete study protocol is available in online supplementary appendix 2.

Setting

All delivery wards in Sweden have been invited to participate in the trial. Presently, three sites are recruiting: Danderyd, Falun, and Helsingborg. All sites are located within large regional or university-affiliated hospitals and have immediate access to a specialist obstetrician or senior registrar, anaesthesiologist, operating theatre and a neonatal intensive care unit. Danderyd has approximately 6500 annual deliveries, of which 300 are VE in nulliparous women, whileFalun and Helsingborg each have approximately 3500 annual deliveries, of which 150 are nulliparous VE. Soon Uppsala and South General Hospital, with almost 12 000 deliveries together, will join the trial.

Characteristics of participants and informed consent

All women expecting their first child and planning to deliver vaginally at the study sites are invited to participate. Written and oral information is given and written consent is obtained by midwives and physicians at regular visits to antenatal care from gestational week 24. Women are also approached at visits to the hospital before delivery. Written information and consent forms are at present available in Swedish and English (online supplementary appendix 3). Signed informed consent forms are forwarded to the research midwife or principal investigator at each site and documented in the woman's medical record. Women with contraindications to VE will not be invited to participate in the trial, neither will women with previous surgery for incontinence or pelvic organ prolapse. Ethical approval has been given to invite women in labour, if adequate pain relief has been given, and there is enough time to obtain informed consent. Inclusion and exclusion criteria are listed in table 1.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Nulliparous woman Singleton, live fetus in cephalic presentation Gestational week 34+0 or more Indication for vacuum extraction Signed informed consent	Previous surgery for incontinence or prolapse

Criteria to be verified by the attending physician at randomisation include signed informed consent, indication for VE and a cephalic singleton live fetus, gestational week 34+0 or more, as well as the absence of previous surgery for incontinence or prolapse.

Description of the intervention and comparison

The decision to assist the delivery by VE is made at the attending physician's discretion. In all women, the urinary bladder should be emptied by catheterisation and adequate pain relief is recommended, prior to application of the vacuum cup. Pain relief may consist of epidural anaesthesia, a pudendal block or local infiltration.

For women allocated to 'lateral episiotomy', a lateral episiotomy is performed as follows.

Local anaesthesia is recommended, injecting mepivacaine, lidocaine or similar local anaesthetic in the hymeneal plane, 1 mL subcutaneously at the incision point and 9 mL in a fan-like fashion from the incision point. The vacuum cup is then applied and the extraction is performed synchronously with the contractions and pushing efforts, until the cup is visible in the vaginal opening, which corresponds to the crowning head.

Lateral episiotomy is then performed using specific episiotomy scissors, Mayo scissors or similar scissors (figure 1).

- Distance from incision point to the posterior fourchette: at least 1 cm, up to 3 cm.
- Angle from the sagittal or parasagittal plane: 60° (45°–80°, aim at the ischiadic tuberosity).
- Length of the incision: 4 cm (3–5 cm).

For women allocated to 'no episiotomy', the perineum will possibly remain intact or tear spontaneously. The operator may only perform episiotomy if severe fetal distress is suspected or on the clinical judgement that extensive perineal injury cannot be avoided. These exceptions should comprise ideally around 10%, but at the most 30% of the VE, if practice is unchanged. Any episiotomy should be lateral. Episiotomy rates in trial participants and non-participants will be followed continuously by the principal investigators.

All women will receive perineal protection using verbal guiding and manual support of the perineum during the delivery of the fetal head and body. The third stage, examination and diagnosis of perineal tears, is managed according to clinical routine. The clinical diagnosis of OASIS is our primary outcome. Adequate pain relief should again be offered to enable a thorough clinical

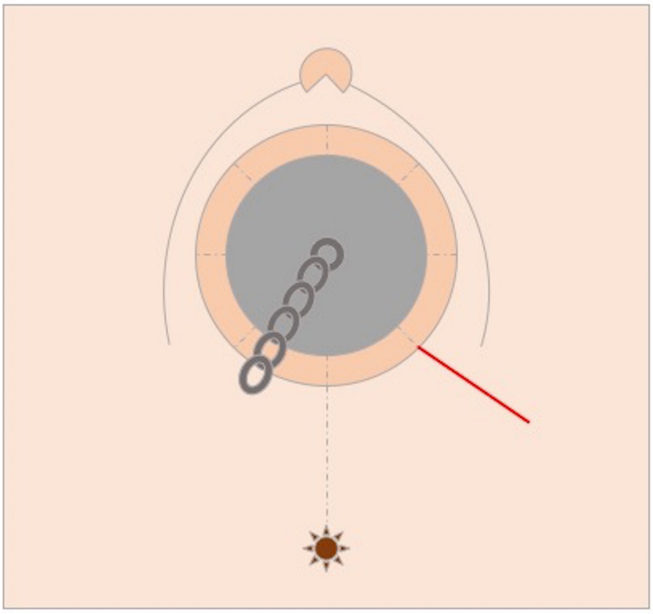

Figure 1 Schematic illustration of a lateral episiotomy in the lateral Episiotomy or not in Vacuum Assisted delivery in nulliparous women (EVA) trial.

bidigital rectal/vaginal examination to reveal any injury to the sphincter muscles or rectum. The diagnosis is confirmed by a specialist gynaecologist/obstetrician or senior registrar. Suturing of OASIS is performed by a specialist gynaecologist/obstetrician or senior registrar and managed according to clinical routine or as suggested in the standard operating procedures.

Primary and secondary outcomes

The primary outcome is OASIS, including third-degree and fourth-degree perineal tears, engaging the external or internal anal sphincter muscles, anal epithelium, or rectum (International Classification of Diseases 10 code O70.2 or O70.3). Diagnosis is made by clinical examination by a specialist obstetrician/gynaecologist or senior registrar.

Short-term secondary outcomes are other degrees of perineal injury, blood loss post partum, complications to episiotomy or perineal injuries such as dehiscence or infection, Apgar score, umbilical artery pH <7.05, shoulder dystocia, admission to the neonatal ward, neonatal injury (scalp trauma, obstetric brachial plexus palsy, cerebral injury, hypoxic ischaemic encephalopathy, respiratory distress and fractures as diagnosed by the neonatologist), duration of hospital stay after delivery, perineal pain and childbirth experience 1–3 days after delivery by Visual Analogue Scale. The data will be collected from the Swedish Pregnancy Register and the National Quality Register for Neonatal Care. Information from maternal and neonatal medical records is automatically forwarded to the registers when the medical records are signed for archiving. The Swedish Pregnancy Register covers 90% of pregnancies in Sweden and virtually all pregnancies at the study sites.[41] The register consists of three parts: the Swedish Maternal Health Care Register, launched in 1999, the Swedish National Quality Register for Prenatal Diagnosis, with data from 2010, and the Obstetric Register, which started in 2013. The three registers, thus, provide detailed information of pregnancies, labours and the postpartum period. The National Quality Register for Neonatal Care covers all 37 neonatal wards and neonatal intensive care units in Sweden since 2012, and consists of data from newborns admitted to hospital care from birth until 28 days of age. The primary outcome OASIS and trial-specific data not available from the registers will be collected in electronic case report forms supplied and monitored by Karolinska Trial Alliance.

Medium-term secondary outcomes, to be assessed by clinical examination and sonographic imaging 6–12 months after delivery in at least one study site, are effects on the pelvic floor anatomy. The OASIS diagnosis and the type of episiotomy will be quality controlled. Descriptive data on pelvic floor muscle injury will be collected, specifically injuries to the sphincters and the levator ani muscle. The women at this site will undergo a structured pelvic examination performed by consultant gynaecologists in an independent centre for pelvic floor disorders, including measurement of any scar, a clinical assessment of pelvic floor muscle function by a six-point muscle strength score, prolapse staging by the pelvic organ prolapse quantification system and a high-resolution two-dimensional perineal and three-dimensional endovaginal and transrectal ultrasound. Data from this follow-up will be collected using electronic case report forms supplied and monitored by Karolinska Trial Alliance.

Medium-term and long-term secondary outcomes, to be assessed by web-based questionnaires, are duration of pain medication after delivery, symptoms regarding anal and urinary incontinence, bowel function, prolapse and sexual function at baseline, 2 months (up to 6 months), 12 months (up to 18 months) and 5 years (up to 5 years and 6 months) after delivery. The questions are based on the questionnaires used by the Swedish Perineal Tear Register, and will be distributed at identical intervals (baseline, 2 and 12 months postpartum) as well as after 5 years. Anal incontinence is assessed by Wexner score in these questionnaires.[42] Childbirth experience will be assessed at 2 months post partum using the revised short form of the Birth Satisfaction Scale and the Childbirth Experience Questionnaire.[43 44] The questionnaires 'Female Sexual Function Index' and 'Female Sexual Distress Scale' will be used for in-depth assessment of sexual function at baseline, 1 and 5 years.[45–47] Quality of life will be measured using the questionnaire EuroQoL-5D-5L at baseline, 1 and 5 years.[48] The questionnaires are administered by an independent provider of patient surveys and data are forwarded to Karolinska Trial Alliance. We will also assess mode of delivery, episiotomy and OASIS in the subsequent pregnancy at 5 years and 10 years after the index delivery by using data from the Swedish Pregnancy Register. The schedule of all follow-up assessments is illustrated in table 2. All collaborators have signed or

Table 2 Schedule of enrolment, interventions and assessments

	Study period							
	Enrolment	Allocation	Postallocation					Close-out
Time point	−4 months	0	0 month	2 months	6 months	1 year	5 years	10 years
Enrolment								
Information	x							
Informed consent	x							
Inclusion/exclusion criteria	x							
Randomisation		x						
Interventions								
Episiotomy		x						
No episiotomy		x						
Assessments								
Background variables	x*		x†					
Data from Pregnancy register (primary and secondary endpoints)			x‡§				x¶	x¶
Data from SNQ on neonatal outcome (secondary endpoints)			x					
Questionnaire BR 1**			x					
Questionnaires FSFI+FSDS			x			x	x	
Questionnaire EuroQol-5D-5L			x			x	x	
Questionnaire BSS-R				x				
Questionnaire CEQ 2.0				x				
Questionnaire BR 2†† (8 weeks)				x				
Questionnaire BR 3‡‡ (1 year)						x	x	
Ultrasound evaluation					x			
POP-Q score					x			
Measurements of scar					x			
Questionnaire Q-SOPhIE					x			
Serious adverse events§§		x	x	x	x	x		

*Maternal age, country of birth, weight and height at registration in the antenatal clinic.
†Use of oxytocin, use of regional or local anaesthesia, birth weight, head circumference, neonatal length, second stage duration, indication for vacuum extraction, fetal position and station, operator skills, number of pulls, use of sequential instruments.
‡Perineal injury, blood loss and neonatal outcomes (Apgar score, umbilical artery pH and birth-related diagnosis).
§Birth experience, duration of hospital stay.
¶Mode of delivery, episiotomy and OASIS in a subsequent pregnancy.
**'Information about your health before pregnancy'.
††'Your evaluation of the treatment of perineal injury (approximately 8 weeks)'.
‡‡'Your evaluation of the treatment of perineal injury (approximately 1 year)'.
§§Serious adverse events (death, intensive care, disability or other important serious medical event) will be reported continuously from allocation until close-out in a separate form.
OASIS: obstetric anal sphincter injury. SNQ: National Quality Register for Neonatal Care, BR: Bristningsregistret (Perineal tear register), FSFI: Female Sexual Function Index, FSDS: Female Sexual Distress Scale, Euro-Qol-5D-5L: European Quality of Life-5 Dimensions-5 Levels, BSS-R: Birth Satisfaction Scale-Revised, CEQ: Childbirth Experience Questionnaire, POP-Q: Pelvic Organ Prolapse Quantification system, Q-SOPhIe:Questionnaire on Symptoms of Obstetric Perineal Injuries

are obliged under law to keep data confidential during and after the trial.

Adverse events, data collection and safety

All randomised women are offered a clinical (apart from the trial) follow-up at 6 months and free and easy access to medical care in association with the episiotomy or perineal tear at the study site during the study period of 5 years. All women will receive postpartum care as individually needed. Serious adverse events, such as death, a life-threatening event, admission to intensive care, persistent or significant disability or incapacity, wound

dehiscence, re-operation, re-admission, intravenous antibiotics, or other medically important events, will be reported in a separate form and evaluated by the sponsor and principal investigators continuously. The Karolinska Trial Alliance will monitor the trial conduct, as well as data collection and safety after start-up, midterm and before closure at each site, covering 20% of randomised women. Karolinska Trial Alliance will also manage important study protocol modifications and communicate these to relevant parties.

Statistical methods

Baseline data will be summarised by descriptive statistics as appropriate; mean and SD, median, upper and lower quartiles, minimum and maximum or frequency tables, stratified by the two arms.

Data will be analysed by intention to treat and per protocol. The primary outcome variable, clinical diagnosis of OASIS, will be presented in numbers as incidence rate in the two allocation groups (intention to treat) and according to received treatment (per protocol). The protective effect of lateral episiotomy will be calculated as a relative risk of OASIS with 95% CIs, adjusting for study site and other possible factors not balanced by randomisation.

Further analyses will compare secondary outcomes using test of proportions, t-test and logistic regression depending on variable characteristics. In the per-protocol analysis of OASIS, we will adjust for possible confounders/effect modifiers such as study site, country of birth, maternal body mass index, operator experience, long duration of labour and second stage, epidural, use of oxytocin, fetal birth weight, head circumference, station and position. We also aim to create a prediction model of the protective effect of lateral episiotomy to support clinical decisions.

Outcomes based on evaluation scores will be analysed by non-parametric tests and paired analyses for change over time in the subgroups using sign test. Details of the statistical analysis will be supplied in the statistical analysis plan, to be finalised in collaboration with statisticians from the Karolinska Institute in a separate document before the data lock.

Sample size calculation

The sample size has been calculated based on data from Lund *et al*, suggesting a 50% reduction of OASIS in VE, when lateral/mediolateral episiotomy is performed.[16] The average rate of OASIS in VE in Sweden was 12.4% in 2016 according to the Swedish Medical Birth Register. A reduction of OASIS from 12.4% to 6.2% can be detected with 80% power and less than 5% risk of alpha-error ($p<0.05$) with 355 women in each group using χ^2 test comparing two independent proportions in a two-sided test (3% missing outcome). A smaller reduction is clinically valuable, although the risk–benefit relationship between receiving a prophylactic episiotomy and the chance of an intact perineum may limit the feasibility of a larger trial in a setting with a restrictive episiotomy policy. We have obtained ethical approval to randomise a total of 1400 women, which enables us to detect a reduction in OASIS rate at VE from 12.4% to 7.8%.

Interim analyses

The Karolinska Trial Alliance will monitor primary outcome data using the electronic case report forms, in which the diagnosis of OASIS is registered. When 100 women have been randomised, we will perform a safety analysis to verify adherence to protocol and collate serious adverse events. We will perform a first interim analysis when 350 women have been randomised, to detect a possible OASIS prevalence reduction from 12.4% to 2.5% with 80% power and $p<0.01$, in concordance with the pronounced reduction, observed in the Dutch register study by van Bavel *et al*.[15] If a reduction of OASIS is achieved at this level, the trial will be discontinued and modified, as the clinical equipoise has been sufficiently disturbed. A second interim analysis will be performed when 710 women have been randomised, to detect a possible 50% reduction from 12.4% to 6.2% with 80% power and $p<0.05$. Similarly, the trial will be stopped if a 50% reduction is detected. If feasible, we will continue the trial until 1400 women have been randomised. Depending on the size of the delivery ward, each site will contribute with approximately 5% of nulliparous women giving birth vaginally (70–200 patients annually). Inclusion rate is expected to be two to three patients per week at a site with 300 annual VEs in nulliparous women, if 50% of women accept participation.

Patient and public involvement

There is no applicable Swedish patient organisation, but prevention of maternal birth injuries has been ranked the most important area of research by patients and unbiased professionals.[49] Ethical approval was obtained from a board composed of professionals and lay men and women, also considering non-professional opinions. Pregnant women are generally curious about the trial and the majority of approached women consent to participate, particularly motivated by a thorough follow-up no matter what perineal injury. The interest from pregnant women is consistent with the observation that 85% of invited women agreed to participate in the pilot RCT by Murphy *et al*, although the rationale for participation may have been the chance to avoid an episiotomy in their setting.[22] The burden of the intervention will be assessed in the secondary outcomes. Results from this trial will be made available to study participants through communication in public media.

Ethics and dissemination

Previous register studies and guidelines all point towards a reduction in OASIS if episiotomy is performed at VE in nulliparous women, as described above. Reintroducing this routine demands a randomised trial and a thorough follow-up to assess the consequences.

Swedish maternity wards should provide an excellent setting to perform a randomised trial of routine lateral episiotomy versus no episiotomy at VE in nulliparous women, given the low episiotomy rate and the relatively high prevalence of OASIS. We expect strong adherence to non-intervention in the control group, facilitating the detection of any difference in OASIS incidence. The timing with new guidelines to consider episiotomy further improves the setting of the study.[17 18] The phrase 'to consider' episiotomy is used deliberately to keep recommendations weak. Yet, it is crucial to undertake and complete the trial before these new guidelines are interpreted as recommendations despite low-grade evidence and lack of long-term follow-up.

Then again, the low episiotomy rate may limit the feasibility of the study. A survey regarding episiotomy preferences and indications was performed in 2012 among 297 delegates at the biennial Nordic Congress of Obstetrics and Gynaecology.[24] Only 17% of the 54 participating Swedish doctors perceived instrumental delivery as an indication for episiotomy, while fetal distress was the most accepted indication. Consequently, 87% of the Swedish doctors never, seldom or only sometimes performed an episiotomy at VE. Thus, experience from episiotomy may be lacking, which will require education and training at the sites when the study is being implemented.

Prior to the previously described British pilot RCT, Macleod and Murphy performed a survey among 1631 obstetricians and specialist registrars in the UK and Ireland with regard to operative vaginal delivery and the use of episiotomy.[22 50] The great majority (72%) reported a restrictive attitude towards use of episiotomy in VE and over 65% said that they would be happy to participate in an RCT of restrictive versus routine use of episiotomy at operative vaginal delivery. We estimate that a similar proportion of Swedish doctors and midwives hold the same view, although personal preferences may hamper recruitment.

Considering the admitted knowledge gap regarding effectiveness and consequences of routine lateral/mediolateral episiotomy in operative vaginal deliveries, we anticipate broad interest in the results from our lateral Episiotomy or not in Vacuum Assisted delivery in nulliparous women (EVA) trial.[9 16 19–21] Being a non-commercial academic study, the investigators will author the results adhering to the authorship criteria recommended by the International Committee of Medical Journal Editors. We intend to disseminate the results by publication in peer-reviewed medical journals and public press, and by presentations at national and international congresses. Data can be made available for future meta-analyses to improve informed practice.

Consent for publication

If case reports will be published, consent will be obtained from relevant parties.

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Contributors SB and VA are investigators and responsible for the implementation of the trial, and manuscript draft and revision. ÅL and SH are principal investigators at Helsingborg and Falun sites and responsible for implementation of the trial and manuscript draft and revision. SK is responsible for the design, implementation and investigations in the sub-study of pelvic floor anatomy at 6–12 months after delivery. HKK is responsible for the manuscript revision, funding and study design. SBW is overall responsible for the implementation of the trial, manuscript draft and revision, funding, study design and the original idea of the study. All authors have participated in manuscript writing and have approved the final version.

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Competing interests None declared.

Patient consent for publication Not required.

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Provenance and peer review Not commissioned; externally peer reviewed.

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