Standardized episiotomy with a new device: BasIQ

Published: 07-03-2014
Last updated: 24-04-2024

To assess if the *BasIQ* makes a standardized incision of 4 cm.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of labour and delivery
Study type	Interventional

Summary

ID

NL-OMON39695

Source
ToetsingOnline

Brief title
Pilot study BasIQ

Condition

- Maternal complications of labour and delivery

Synonym
cut, Episiotomy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,IQ Medical Ventures

Intervention

Keyword: Device, Episiotomy, Incision, Standardized

Outcome measures

Primary outcome

Primary: The main endpoint will be whether there is a standardized incision of

4 cm in women with an episiotomy performed with the *BasIQ*.

Secondary outcome

Secundary: 1.Device safety for caregiver 2.Device safety for the neonate

3.Wound infection 4.Morbidity related to episiotomy 5. Caregiver experiences 6.

wound healing

Study description

Background summary

The episiotomy is the most performed surgical intervention in the world. However, in modern obstetrics, this old procedure needs to be optimized while the scissors used for an episiotomy lack precision. We developed a new device in order to create a standardized incision with better healing outcomes.

Study objective

To assess if the *BasIQ* makes a standardized incision of 4 cm.

Study design

Prospective cohort pilot study

Intervention

Incision with the BasIQ

Study burden and risks

The *BasIQ* is invented to make a precise, sharp, 4cm incision, and is easy to use, with better healing outcomes and less complications with similar safety. Although the device has no CE mark yet, we believe that after various animal testing and expert opinions, a clinical pilot study can prove the feasibility

of this new device. While eligible women are counselled extensively, they will be aware of the purpose of the pilot study. In addition participating women will know that if necessary, the episiotomy will be performed and sutured by an expert.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All women aged 18 years and older who are pregnant and intend to deliver vaginally (for the first time) in the AMC

Exclusion criteria

1.Insufficient knowledge of the Dutch language
2.Coagulation disorders
3.Expected wound healing problems (diabetes, venous insufficiency, immune suppression)
4.Thrombocytopenia (pre-eclampsia, HELLP syndrome, idiopathic thrombocytopenia

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2015
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	BasIQ
Registration:	No

Ethics review

Approved WMO Date:	07-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-08-2014

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL41883.018.13