BasIQ-4® a new approach towards performing episiotomy

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21926

Source
NTR

Brief title
BasIQ-4

Health condition

women pregnant and scheduled to deliver “at term” of a fetus in cephalic presentation

Sponsors and support

Primary sponsor: BasIQ B.V.
Source(s) of monetary or material Support: BasIQ B.V.

Intervention

Outcome measures

Primary outcome

to further evaluate and monitor the safety and performance of the “BasIQ-4®” in a population of women delivering in general hospitals in The Netherlands when used as intended

Secondary outcome

• To confirm the acceptability of the identified residual risks associated with the use of the “BasIQ-4®”.
• To identify not yet identified risks.
• To generate results with this study that will initiate further scientific investigation especially between the BasIQ-4® and episiotomy scissors.

Study description

Background summary

The episiotomy is the most performed surgical intervention in the world. However, making an incision with scissors is against surgical principles, as a cut wound using BasIQ-4® theoretically results in better wound healing. We developed the “BasIQ-4®” in order to create a (medio)lateral incision of approximately 4 cm from dorsal to ventral/lateral to median towards the vaginal introitus (from the perineum towards the posterior fourchette of the vagina). From the point with the lowest tissue tension to the direction of the highest tissue tension. As a consequence of starting the incision point dorsal it is possible to make a (medio)lateral incision in one single movement.

Study objective

to further evaluate and monitor the safety and performance of the “BasIQ-4®” in a population of women delivering in general hospitals in The Netherlands when used as intended

Study design

time of delivery

Intervention

The “BasIQ-4” is designed to perform a (medio)lateral episiotomy of approximately 4 cm

Contacts

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Scientific

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Eligibility criteria

Inclusion criteria

All women aged 18 years and older who are pregnant and scheduled to deliver “at term” of a fetus in cephalic presentation and intend to deliver vaginally (for the first time) and who are willing and able to give written informed consent.

Exclusion criteria

Insufficient knowledge of the local language
Prior vaginal delivery in anamnesis
Coagulation disorders
Expected wound healing problems
diabetes mellitus
venous insufficiency
immune suppression (e.g. HIV infected women, women using immunosuppressive drugs)
Thrombocytopenia
pre-eclampsia/HELPP syndrome
Forceps delivery
Vulnerable people

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-08-2020
Enrollment:	100
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

Ethics review

Positive opinion

Date:	06-05-2020
Application type:	First submission

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
NTR-new	NL8601
Other	METC Maxima Medisch Centrum : w19.044

Study results

Summary results
https://iq-medicalventures.com/wp-content/uploads/2019/11/Elkerliek-Hospital-case-report.pdf