BasIQ-4® a new approach towards performing episiotomy

Published: 20-12-2019
Last updated: 10-04-2024

Primary objectives: The main objective of this Post Market Clinical Follow-Up (PMCF) study is 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...

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

Summary

ID

NL-OMON49943

Source
ToetsingOnline

Brief title
BasIQ-4® PMCF Study

Condition

- Maternal complications of labour and delivery

Synonym
cut, episiotomy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: episiotomy, incision, mediolateral, new device

Outcome measures

Primary outcome

Primary endpoints:

Device Success, achieved if all three below conditions are met:

• BasIQ-4® makes an incision in one continuous movement (without interruption).

• The length of the scar caused by BasIQ-4® as measured at the 6 week visit is between 3 and 5 cm.

• Absence of any Serious Adverse Event related to BasIQ-4® occurring up to the 6 week visit for neonate, caregiver or for mother (other than the intended episiotomy itself) as adjudicated by the Data Monitoring Committee.

Secondary outcome

Secondary endpoints:

• BasIQ-4® makes an incision in one continuous movement (without interruption).

• The length of the scar caused by BasIQ-4®, as measured at the 6 week visit is between 3 and 5 cm.

• Serious Adverse Event related to BasIQ-4® occurring up to the 6 week visit for neonate, caregiver or for mother (other than the intended episiotomy itself) as adjudicated by the Data Monitoring Committee.

• Angle of the scar caused by BasIQ-4®, as measured at the 6 week visit.

• Distance (mm) from the endpoint of the scar caused by BasIQ-4® incision to

the midline of the posterior fourchette, as measured at the 6 week visit.

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

Primary objectives:
The main objective of this Post Market Clinical Follow-Up (PMCF) study is 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 (solely used by professional users and in accordance with the PMCF study protocol and the Instructions For Use).

Secondary objectives:
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 design

Prospective multicenter interventional study (open label single arm)

Intervention

Episiotomy

Study burden and risks

Episiotomy is the most performed surgical intervention in obstetrics. There are huge geographical differences in the prevalence of episiotomy both within Europe and worldwide. Women who intend to deliver vaginally have a chance of 21-39% to receive an episiotomy in The Netherlands.
This means approximately 34.000 episiotomies are performed in The Netherlands each year, i.e. four episiotomies every hour. The burden of participating in this pilot study will be the novelty of the device. The results of the pre-CE clinical investigation showed that with the device one is able to perform a safe (safe for patient, neonate and caregiver) episiotomy. Theoretical benefit of the device is better healing outcome (straight incision/scar with sharp wound edges) because of a knife cut wound instead of a wound made by scissors. Women will be informed by their research physician. Since eligible women are informed orally and in writing extensively, they will be aware of the purpose of this PMCF study.

Contacts

Public
BasIQ B.V.

World Trade Center, Beursplein, Suite 1960 37
Rotterdam 3011 AA
NL
Scientific
BasIQ B.V.

World Trade Center, Beursplein, Suite 1960 37
Rotterdam 3011 AA
NL

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 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 phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2020
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	BasIQ-4
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-12-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	18-06-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	28-10-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL70216.015.19
Other	NL8601