Enhanced recovery after caesarean section.

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In this study, we would introduce and evaluate an enhanced recovery programme designed by a multidisciplinary team for patients undergoing elective CS in our tertiary obstetric unit.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48271

Source
ToetsingOnline

Brief title
Enhanced recovery after caesarean section

Condition

- Other condition

Synonym
caeserean section

Health condition

voortplantingsstelsel keizersnede

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: caesarean section, enhanced recovery, fast recovery

Outcome measures

Primary outcome

- Pain measured by a numeric rating scale (NRS)

- Use of pain medication

- Patient satisfaction measured by a numeric rating scale (NRS)

- Length of hospital stay

Secondary outcome

- operative details

- the number of readmissions

- postoperative complications (bleeding, wound infection, urinary infection,

urinary retention, thrombosis)

Study description

Background summary

Caesarean section (CS) is one of the commonest surgical procedures and most patients are discharged at least two days post-surgery [6]. CS is associated with prolonged hospital stay in comparison to spontaneous birth and the majority of women remain in hospital for at least two days after a planned CS procedure [3].
The widespread adoption of enhanced recovery (ER) programmes in various surgical specialties had resulted in patient benefits including reduced morbidity, reduced length of stay and an earlier return to normal activities. Although very few obstetric units currently practise enhanced recovery (ER) for obstetric surgery, there is widespread interest and support for it. Moreover, along with the increased financial pressures many units have considered introducing such a programme for obstetric surgery. The aim of enhanced recovery is to optimise multiple aspects of patient care to improve recovery and so facilitate earlier discharge [1,6]. Until recently there has been little

interest in ER for obstetric surgery. However, next-day discharge is in keeping with National Institute for Health and Care Excellence (NICE) guidance and the young and fit obstetric patient population has many characteristics that should make implementation beneficial [6].
According to Wrench et al., the proportion of women discharged on day 1 increased from 1.6% to 25.2% after introducing an ER programme [6]. Furthermore, application of ER programmes after caesarean delivery is associated with improved maternal satisfaction and more positive feelings toward the relationship with the new-born [4].

Study objective

In this study, we would introduce and evaluate an enhanced recovery programme designed by a multidisciplinary team for patients undergoing elective CS in our tertiary obstetric unit.

Study design

Observational study

Study burden and risks

Allowing patients to go home the day after an elective CS is supported by recommendations from the Nation Institute for Health and Care Excellence (NICE) guidance [2]. Early discharged from hospital and follow-up at home is not associated with more infant or maternal readmissions.
All participants fill out short questionnaires at two different intervals, 24 hours and 1 week after the caesarean section. No extra visit to the hospital is needed.

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

Women planned for a caesarean section

Exclusion criteria

- Women who do not speak Dutch
- Women younger than 25 years
- Women with a history of a midline laparotomy
- Women with deep invasive endometriosis
- Women with contra-indications for opioids
- Total blood loss of 1000cc or more during surgery

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Not approved

Date:	18-03-2019
Application type:	First submission
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	NL69340.015.19