

Investigation of the cosmetic result of caesarean section scars

Submission date 30/11/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/05/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/05/2013	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.studies-obsgyn.nl/>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Techniques for skin closure after a caesarean: the cosmetic result

Acronym

SCACS-trial (Skin Closure After Caesarean Section)

Study objectives

We hypothesise that closure of the fat layer and closure of the skin with a suture will yield a better cosmetic result.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethical Commission of the VU Medical Centre on the 23rd November 2006 (ref: 2005/205).

Study design

Multicentre prospective randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information short and full version, cited on the following URL: <http://www.studies-obsgyn.nl/>

Health condition(s) or problem(s) studied

Caesarean section

Interventions

Pre-operative the patient will be randomly assigned to four categories:

1. No closure of the fat layer and skin closure with staples
2. No closure of the fat layer and skin closure with stitches
3. Closure of the fat layer and skin closure with staples
4. Closure of the fat layer and skin closure with stitches

The primary outcome is the cosmetic result measured with the Patient and Observer Scar Assessment Scale, in which the patient and the investigator complete a questionnaire. The

wound assessment will be performed six months after the caesarean. Secondary outcomes include post-operative pain, wound complications, such as dehiscence, infection, seroma or haematoma, material reaction, operating time for the skin closure and costs.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Cosmetic outcome, measured with the Patient and Observer Scar Assessment Scale six months after caesarean.

Secondary outcome measures

1. Post-operative pain
2. Operating time
3. Costs
4. Wound complications, such as infection, dehiscence, haematoma and seroma

Overall study start date

02/02/2007

Completion date

02/09/2008

Eligibility**Key inclusion criteria**

1. Pregnant women
2. Older than eighteen years
3. Planned for having a caesarean section
4. Give informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

125

Key exclusion criteria

Women with a previous abdominal operation, including caesarean section.

Date of first enrolment

02/02/2007

Date of final enrolment

02/09/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Spaarnepoort 1

Hoofddorp

Netherlands

2134 TM

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands)

Sponsor details

c/o Irene Wiersma

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

Sponsor type

Hospital/treatment centre

Website

<http://www.studies-obsgyn.nl/>

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Departments of Obstetrics and Gynaecology at:

Funder Name

The Spaarne Hospital (The Netherlands)

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2012		Yes	No