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Investigation of the cosmetic result of caesarean section scars

Submission date 30/11/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/05/2008	**Overall study status** Completed	
Last Edited 08/05/2013	**Condition category** Pregnancy and Childbirth	

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