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The effect of triclosan coated sutures in wound healing: a double blind randomised prospective pilot study

Submission date
16/07/2007

Recruitment status
No longer recruiting

Registration date
16/07/2007

Overall study status
Completed

Last Edited
27/10/2021

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

NL957 (NTR983)

Study information

Scientific Title
The effect of triclosan coated sutures in wound healing: a double blind randomised prospective pilot study

Study objectives
Triclosan coated sutures might have an positive effect on wound healing and thus can improve scar quality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised, double blinded, active controlled, parallel group, trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Coated sutures, triclosan, vicryl plus, wound healing

Interventions
Standard suture on control site versus triclosan coated suture on study site.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Triclosan coated sutures

Primary outcome measure
Wound healing:
Wound dehiscence and complications are registered.

Secondary outcome measures
Scar quality:
1. Colorimetric measurement one month after surgery. Measurements are performed under standard conditions at four fixed test sites
2. Subjective scar assessment by patients and one primary observer using the Patient and Observer Scar Assessment Scale (POSAS)

Overall study start date
11/07/2006

Completion date
11/08/2007

Eligibility

Key inclusion criteria
1. Women between 16 and 65 years of age with bilateral breast size higher than cup DD
2. Clinical complaints such as intertrigo, head neck and/or shoulder complaints
3. Undergoing a breast reduction

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
26

Total final enrolment
26

Key exclusion criteria
Patients with:
1. Diabetes
2. Skin diseases
3. History of keloid formation
4. Use of corticosteroids and other immunosuppressive medication
5. Metabolic and/or degenerative diseases

Date of first enrolment
11/07/2006

Date of final enrolment
11/08/2007

Locations

Countries of recruitment
Belgium

Netherlands

Study participating centre
Riemsterweg 29
Bilzen
Belgium
3740

Sponsor information

Organisation
University Hospital Maastricht (The Netherlands)

Sponsor details
Department of Plastic Surgery
Maastricht
Netherlands
6200 MD

Sponsor type
Hospital/treatment centre

Website
http://www.unimaas.nl/

ROR
https://ror.org/02d9ce178

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

University Hospital Maastricht (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
Not provided at time of registration

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		01/06/2009	27/10/2021	Yes	No