The prevention of hypertrophic scar formation by the application of platelet gel.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Soft tissue neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON29794

Source
ToetsingOnline

Brief title
platelet gel

Condition

- Soft tissue neoplasms benign
- Epidermal and dermal conditions

Synonym
excessive scarring, hypertrophic scarring

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Ortomed BV

Intervention

Keyword: breast reduction, hypertrophic scar, wound healing

Outcome measures

Primary outcome

At two days and six weeks the scars, lateral, medial, left and right, will be investigated for complications like hematoma, infection or dehiscence.
At three months and a year clinically the height of the scars will be scored as normal, hypertrophic (raised above skin level, but within the confines of the original lesion) or keloid (raised above skin level, but beyond the confines of the orignal lesion). The width of the scar will be measured with a ruler and width and height will be studied intradermally with ultrasound (10 MHz). Standardized pictures will be made at 85 cm of the scar. The investigations will be done on a standard measuring point at three centimer of the outer border of every scar.

Secondary outcome

At two days, three months and a year scar biopsies will be taken form the lateral scars. They will be snap frozen and stored in - 80C for further usage. The biopsies will be sectioned and stained with antibodies.
Epidermis: MIB-1 against Ki-67 to score keratinocyte proliferation, Ks8.12 against cytokeratin 16 to score keratinocyte differentiation and CD-1A against Langerhans cells.
Epidermis and dermis: antilibodies against TGF-β1,2,3, PDGF, IL-1α, IL-4 en IGF-1,2. These growth factors are associated with excessive scar formation. If the clinical results are hopefull extra research will be done on messenger RNA

expression from the different growth factors.

Study description

Background summary

Excessive scar formation following burns, trauma or surgery, can be a big functional, cosmetic and psychologhical problem for patients, especially for children and young adults.
To prevent this scar formation in the skin (hypertrophic scars and/or keloids), but also in tendons, nerves or bowels, is an important scientific challenge.

Study objective

In previous studies is found that the sequence of processes leading to excessive scar formation starts during the operation. Abnormal epidermal-dermal interactions and excessive immune reactions seem to play an important role. On theoretical base an acceleration of the healing processes could give a better scar. In this project it will be investigated if the application of an autologous platelet gel in the wound during the operation can prevent the formation of scar hypertrophy.

Study design

The clinical part of the study will be at the department of Plastic Surgery in the University Medical Center Groningen. The breast-reduction scar model will be used. 35 patients will be included.
Half of the caudal infra-mammary wound (rigth medial and left lateral or vice versa) of every breast will be treated with the gel. The study is prospective, randomised and blinded. Patients will be controlled at two days, six weeks, three months and a year.

Study burden and risks

The breast-reduction operation and post-operative controls are conform normal protocol. The control sessions will take more time and at two days, three months and a year biopsies will be taken.
From autologous platelet gel, no adverse effects were reported in literature. Off course to predict the exact effect in normal wound healing is not possible.

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

In this study 35 healthy women will be included who will be operated for breast-reduction surgery. The technique used must result in an infra-mammary scar. The patients will be older than 18 years of age.

Exclusion criteria

Not healthy enough to undergo the operation. Pregnant women.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2006
Enrollment:	35
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL12635.042.06