Can we predict who will develop a hypertrophic scar or keloid? An observational study on the association of cytokines with hypertrophic scarring and keloid.

Published: 26-05-2008
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Primary objective: to prove or exclude an association between the amount of TFG-*3 in the blood and the development of HTS and keloid.Secundary objectives:- to research the association between collagen composition of the skin and the POSAS score;-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON31687

Source
ToetsingOnline

Brief title
Cytokines and hypertrophic scarring

Condition

- Epidermal and dermal conditions

Synonym
abnormal scarring, pathological scarring

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: NWO,Hartstichting

Intervention

Keyword: Collagen, Cytokine, Hypertrophic scarring, Scarring

Outcome measures

Primary outcome

- Amount of TGF*-3 in the blood;

- Patient and Observer Scar Assessment Scale scores;

- Judgment of quality of wound healing by physician through photographs of the scar.

Secondary outcome

- Amount of TGF*-1 in tissue specimens, blood and drainfluids;

- Amount of TGF*-2 in tissue specimens, blood and drainfluids;

- Amount of TGF*-3 in tissue specimens, blood and drainfluids;

- Amount of PDGF in tissue specimens, blood and drainfluids;

- Amount of chemokines in tissue specimens, blood and drainfluids;

- Amount of hydrocylysines (from which collagen I/III ratio is calculated) in tissue specimens;

- Amount of pyridinoline cross-links per collagen molecule in tissue specimens;

- Ratio collagenous-/non-collagenous proteins in tissue specimens;

- Percentage of patients with HTS;

- Percentage of patients with keloid;

- Sociodemographic information;

- Treatment related data;

- Co-morbidity.

Study description

Background summary

Hypertrophic scars (HTS) and keloid are thickened scars, often with considerable cosmetic and functional morbidity. Individuals who suffer from these types of scarring have a higher POSAS score (score indicating the level of abnormality of a scar) than individuals with normal scars. The process of this type of scarring is unknown. We do know, however, that HTS and keloid contain a higher amount of collagen than normal scars. Collagensyntheses in scars is stimulated by profibrotic cytokines and inhibited by antifibrotic cytokines like TGF-*3. Theoretically, HTS- or keloid-forming skin produces less TGF-*3 than skin that scars normally. Assuming that this difference is visible in the blood as well, the hypothesis of this research is that blood of persons with a high POSAS score (abnormal scars) contains less TGF-*3 than blood of persons with a lower POSAS score (normal scars).

Study objective

Primary objective: to prove or exclude an association between the amount of TFG-*3 in the blood and the development of HTS and keloid.

Secundary objectives:
- to research the association between collagen composition of the skin and the POSAS score;
- to research risk factors for a high POSAS score;
- to give an indication of the incidences of HTS and keloid in the Dutch population.

Study design

Observational study.

Study burden and risks

INTERVENTION
Blood is taken before the operation. During the operation (median sternotomy) tissue specimens of 1x0,5 cm are taken from the rim of the incision. In CABG-procedures a specimen of the venous or, when possible, the arterial graft is taken as well.

NATURE AND EXTENT OF THE BURDEN AND RISKS ASSOCIATED WITH PARTICIPATION, BENEFIT
No serious are associated with participation.
- Blood will be drawn from the iv-line of the patient just before surgery.
- Biopsies are taken during the procedure and will not cause additional complaints or disturb woundhealing.
- In addition to the regular hospital visits, subjects will visit the St. Antonius Hospital 3 times extra for the purpose of this research.

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

- Patient will undergo elective surgery by median sternotomy in the St. Antonius Hospital Nieuwegein

- Patient is older than 18 years

Exclusion criteria

- Incompetent
- Connective tissue disease
- Scarring of surgical site
- Use of steroids
- Participation in other trials

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	27-05-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-09-2008

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL19953.100.07