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Comparing three different materials to treat large, deep burns: a one year follow-up

Submission date
09/12/2018

Recruitment status
No longer recruiting

Registration date
16/01/2019

Overall study status
Completed

Last Edited
27/02/2023

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Mortality after severe burns has been diminishing during the last decades and more attention is paid to the final functional and cosmetic outcome. Gold standard is to use split thickness skin grafts but they are far from optimal. The donor sites of the skin grafts may have wound healing problems and scarring and pigmentation problems. The skin grafts themselves may contract and scarring may form. They are often itchy and dry and need to be constantly taken care of. Sometimes there is not enough healthy skin for grafting. Therefore other materials should be considered and tested. Skin substitute Integra has been on the market for decades but still comparative objective studies are rare. There is some evidence that the use of dermal skin substitutes results in better quality of scars than split thickness skin grafts alone. Dermal substitutes also enable the use of thinner skin grafts with less donor site problems. With a temporary wound dressing the wound may be protected and prepared for final covering. Temporary dressings often support the building of the new tissue but the role of the new tissue underneath the split thickness skin graft in final outcome is not clear. The aim of the study is to compare three very different ways to treat the burn wounds after removal of dead tissue and to see if they have different outcomes one year later cosmetically and functionally. From the skin samples also the differences of the test areas are assessed on tissue and cell level, even on protein or molecular level. The hypothesis is that the skin substitute Integra with a thin skin graft should have the best results of the three test areas.

Who can participate?
Participants are adult patients between 17 and 70 years who are treated in Helsinki Burn Centre for large deep burns over 20 % of body surface area and the test area of the deep burns is located on the front side of the body.

What does the study involve?
Standard treatment of deep burn wounds is compared to two other treatment materials. All participants receive the same treatment, just the order of the used materials vary in the test area.

What are the possible benefits and risks of participating?
The possible benefits are better cosmetic and functional outcome of the operated test areas

compared to standard treatment areas. Possible risks are: risk of wound infection, which is a little increased in the areas of dermal substitute and scarring of the test areas, small additional scars due to biopsies.

Where is the study run from?
Helsinki Burn Centre, Department of Plastic Surgery, Helsinki University Hospital, University of Helsinki, Finland.

When is the study starting and how long is it expected to run for?
The first patient was enrolled 01/05/2001. The series of ten patients was completed 22/9/2004. The analysis of the samples is still going on.

Who is funding the study?
This research has been funded by the Scientific Committee of the Finnish Ministry of Defence and by government subsidies for medical research block grants (EVO).

Who is the main contact?
Dr Heli Lagus (heli.lagus@hus.fi)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DNro 101/E6/2000

Study information

Scientific Title
Comparing Integra, a cellulose sponge and split thickness skin graft in the treatment of large, deep third degree burns in adults: a one year follow-up of a prospective randomised controlled trial.

Study objectives
Integra will result in better quality skin than gold standard split thickness skin graft alone. The long term results one year after operation will show differences in proteomic analyses

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Research Ethics Committee of the Helsinki University Hospital, 22/12/2000, ref. DNro 101/E6 /2000

Study design
Interventional, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Third degree burns

Interventions
Ten burn patients with > 20 % total body surface area deep burns had a test area 15x10 cm of a fascially excised burn wound on the anterior side of the body. Test area was divided into three sections (5x10 cm) and covered with one each: 1) split thickness skin graft (STSG), 2) artificial dermal matrix and 3) a temporary wound dressing of viscose cellulose sponge inducing granulation tissue in a randomized order. The STSG was left intact in place whereas the other two sections with different materials were covered with similar STSGs two weeks later after removal of a protective silicone layer of artificial dermal matrix and after removal of viscose cellulose sponge. All patients received the same treatment, only the order of the materials was randomized. Punch biopsy samples from the test areas were taken on days 3, 7, 14, and 21, 3

months and 12 months after primary surgery. The outcome was assessed at three months and twelve months after primary surgery with Vancouver Scar Scale by an occupational therapist.

Intervention Type
Supplement

Primary outcome measure
1. Clinical, cosmetic and functional outcomes were measured using the Vancouver Scar Scale 3 months and 12 months after primary surgery.
2. Differences in wound healing were measured histologically and immunohistochemically using biopsy samples from the test areas on days 3, 7, 14, and 21, 3 months and 12 months after primary surgery. The following biomarkers were measured:
2.1. HE
2.2. CD31
2.3. CD163
2.4. Alpha SMA
2.5. MIB1
2.6. collagen type IV
2.7. CASP14
2.8. DNAH10

Secondary outcome measures
1. Long term differences in proteins were measured using proteomic analyses performed with Q Exactive Plus (ThermoFisher Scientific) mass-spectrometer operating with a top-5 MS/MS strategy.
1.1. Raw data were identified and quantified with MaxQuant 1.4.0.8 software package.
1.2. Search was performed against the UniProt (www.uniprot.org) human database using the tryptic digestion rule.
1.3. The findings of proteomics were validated with immunohistochemistry of DNAH10 and CASP14.

Overall study start date
01/01/2000

Completion date
31/12/2018

Eligibility

Key inclusion criteria
Participants:
1. Aged between 17 and 70 years
2. Total burned surface area (TBSA) over 20%
3. Burns located on the anterior side of the body.

Test areas:
1. Deep third degree burns requiring fascial excision.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10

Total final enrolment
10

Key exclusion criteria
Patients who did not survive the follow up time.

Date of first enrolment
01/05/2000

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
Finland

Study participating centre
Helsinki Burn Centre, Department of Plastic Surgery, Helsinki University Hospital, University of Helsinki, Finland
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Sponsor information

Organisation
the Scientific Committee of the Finnish Ministry of Defence

Sponsor details
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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
the Scientific Committee of the Finnish Ministry of Defence and government subsidies for medical research block grants

Results and Publications

Publication and dissemination plan
The first part of the study was published in Burns (2013). The second part of the study was published in World Journal of Surgery (2018). The third part of the study concerning the proteomic findings and their immunohistochemical validation with reflection to a skin pathology psoriasis is in a peer review for a scientific paper.

Intention to publish date
01/02/2019

Individual participant data (IPD) sharing plan
The mass spectrometry proteomics data will be available at the time of publication of the article via ProteomeXchange with identifier PXD010852. All other than published de-identified data will be available on request from the authors.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2013		Yes	No
Results article	results	01/04/2018		Yes	No
Basic results		14/12/2018	18/12/2018	No	No
Results article		13/12/2019	27/02/2023	Yes	No