

Subdermal implantation of the collagen-elastin-matrix Matriderm® to improve profile and skin structure of degenerative changes in the midface region [Subkutaner einsatz der kollagen-elastin-matrix Matriderm® zur verbesserung von profil und hautstruktur bei degenerativen veränderungen des mittelgesichtes]

Submission date

15/05/2009

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

31/07/2009

Overall study status

Completed

☐ Statistical analysis plan

☐ Results

Last Edited

31/07/2009

Condition category

Skin and Connective Tissue Diseases

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

DE/CA22/2-2008/KLP

Study information

Scientific Title

Subdermal implantation of the collagen-elastin-matrix Matriderm® to improve profile and skin structure of degenerative changes in the midface region: a non-randomised single arm clinical trial

Acronym

SIMAMID II

Study objectives

Collagen matrices are in clinical use in plastic and burn surgery under split skin for dermal regeneration; in this study we investigate the effects of subdermal implantation of the matrix under healthy skin on mid-face profile, skin quality and dermal architecture.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The local ethics committee (Ethik-Kommission bei der Landesärztekammer Hessen) approved on the 4th June 2008 (ref: FF 29/2008)

Study design

Non-randomised single-arm clinical trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Degenerative structure of profile and/or skin quality in the mid-face, caused by disease or ageing

Interventions

Step 1: Subdermal laminar implantation of a collagen-elastin-matrix on the upper arm

Step 2: Subdermal laminar implantation of a collagen-elastin-matrix on the mid-face region

Skin biopsies (upper arm) before, 6 and 12 months post-operatively.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Matriderm®

Primary outcome measure

Clinical outcome of mid-face region, measured at month 8 after step 1 (upper arm).

Secondary outcome measures

Clinical, histological and cutometric outcome upper arm, measured at month 14 after step 1 (upper arm).

Overall study start date

15/05/2008

Completion date

14/11/2009

Eligibility**Key inclusion criteria**

Healthy adults aged 40 - 65 years, either sex

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Severe allergies
2. Severe acute or chronic diseases
3. Skin infections

Date of first enrolment

15/05/2008

Date of final enrolment

14/11/2009

Locations

Countries of recruitment

Germany

Study participating centre

Klinik für Plastische-, Ästhetische- und Handchirurgie

Offenbach

Germany

63069

Sponsor information

Organisation

Dr Suwelack Skin and Health Care AG (Germany)

Sponsor details

Josef-Suwelack-Strasse

Billerbeck

Germany

48727

Sponsor type

Industry

ROR

<https://ror.org/05hqyp882>

Funder(s)

Funder type

Industry

Funder Name

Dr Suwelack Skin and Health Care AG (Germany)

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