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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	Recruitment status	[_] Prospectively registered
15/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/07/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
31/07/2009	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Henrik Menke

Contact details
Klinik für Plastische-, Ästhetische- und Handchirurgie
Schwerbrandverletztenzentrum
Starkenburgring 66
Offenbach
Germany
63069

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