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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

Study design
Non-randomised single-arm clinical trial

Study type(s)
Treatment

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

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

Completion date
14/11/2009

Eligibility

Key inclusion criteria
Healthy adults aged 40 - 65 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

ROR
https://ror.org/05hqyp882

Funder(s)

Funder type
Industry

Funder Name
Dr Suwelack Skin and Health Care AG (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration