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Fractional photothermolysis versus triple therapy for the treatment of melasma: a randomised controlled trial

Submission date
13/07/2007

Recruitment status
No longer recruiting

Registration date
04/03/2008

Overall study status
Completed

Last Edited
04/03/2008

Condition category
Skin and Connective Tissue Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
fraxel-1

Study information

Scientific Title

Study objectives
Fractional photothermolysis may be an effective and safe alternative for the treatment of melasma and the effect of the treatment with fractional photothermolysis may last longer than the effect of the triple therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Centrale Commissie Mensgebonden Onderzoek (CCMO) on the 19th September 2007 (ref: NL18605.018.07).

Study design
Randomised, controlled, parallel group, observer blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Melasma

Interventions
Subjects will be randomly allocated to one of two groups who receive either triple therapy (bleaching cream [hydrochinon 5%, tretinoin 0.05% and triamcinolon acetonide 0.1% in cremor lanette II]) or fractional photothermilysis using the fraxel laser.

Triple therapy:
The triple therapy will be applied once a day in the evening on all hyperpigmented macules for eight weeks. Follow-up will take 3, 12 and 24 weeks post therapy.

Fractional photothermolysis:
Subject will receive a total of four laser treatments, with two week intervals. A topical anaesthetic ointment will be applied to the skin before treatment. The treated area will be less than 3% of the body surface. Follow-up will take place 3, 12 and 24 weeks post therapy.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Triple therapy bleaching cream (hydrochinon, tretinoin, triamcinolon acetonide)

Primary outcome measure
1. Observer blinded clinical score (Melasma Area and Severity Index [MASI] score), measured before treatment and during 3, 12 and 24 weeks of follow-up
2. Objective colour measurement by reflectance spectroscopy, measured before treatment and during 3, 12 and 24 weeks of follow-up

Secondary outcome measures
1. Visual assessment of side effects and quality of life measurements (skindex):
1.1. Fraxel laser group: after laser treatment and during follow-up (3, 12, 24 weeks)
1.2. Triple group: during follow-up (3, 12, 24 weeks)
2. Registration of side effects noticed by the patient:
2.1. Fraxel group: after laser treatment and during follow-up
2.2. Triple group: after three weeks of treatment by telephone

Overall study start date
20/09/2007

Completion date
01/05/2008

Eligibility

Key inclusion criteria
1. Adult patients with melasma
2. Skin photo type II - V
3. Subjects attending the outpatient department of the Netherlands Institute for Pigment Disorders
4. Aged at least 18 years
5. Subject is willing and able to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
20

Key exclusion criteria
1. Bleaching cream during the past four weeks
2. Local corticosteroids during the past four weeks
3. Subjects with a history of keloids
4. Subjects with active eczema
5. Subjects with active acne in the face
6. Subjects with a history of facial eczema
7. Suspect allergy to lidocaine or the triple therapy
8. Use of roaccutane in the past six months
9. Subjects not competent to understand what is involved
10. Pregnancy
11. Lesion suspicious for malignancy
12. High exposure to sunlight (vacation in southern countries) or ultraviolet (UV) light (UVA or UVB)

Date of first enrolment
20/09/2007

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Meibergdreef 35
Amsterdam
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Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

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