

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

Submission date
13/07/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
04/03/2008

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
04/03/2008

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

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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 [hydroquinon 5%, tretinoin 0.05% and triamcinolon acetonide 0.1% in cremor lanette II]) or fractional photothermolysis 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 (hydroquinon, tretinoin, triamcinolon acetonide)

Primary outcome(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (The Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration