

National trial on home ultraviolet B (UVB) phototherapy for psoriasis

Submission date 13/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 23/04/2010	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

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
NCT00150930

Secondary identifying numbers
NTR30

Study information

Scientific Title

Home ultraviolet B (UVB) phototherapy in psoriasis: effectiveness, quality of life and cost-effectiveness

Acronym

PLUTO

Study objectives

The aim of this study is to compare home UVB phototherapy with the current outpatient UVB phototherapy for patients with psoriasis.

This objective was specified by the following research questions:

1. Is home UVB phototherapy for patients with psoriasis equally as effective as outpatient UVB phototherapy?
2. Does home UVB phototherapy yield a better quality of life than outpatient UVB phototherapy?
3. Are costs for home UVB phototherapy higher, lower or similar to outpatient UVB phototherapy?
4. Is home UVB phototherapy cost-effective?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The final protocol was approved by the Medical Ethics Committees of all participating hospitals.

Study design

Multicentre, randomised, single blinded, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Psoriasis

Interventions

Randomisation to two treatment groups:

1. Home UVB phototherapy
2. UVB phototherapy in the hospital

Both therapies are common practice in the Netherlands.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Psoriasis area and severity index (PASI) and self administered PASI (SAPASI) scores.

Secondary outcome measures

1. Quality of life (36-item short form health survey [SF-36], European quality of life [EQ-5D] instrument, psoriasis disability index [PDI])
2. Cost-effectiveness

Overall study start date

01/10/2002

Completion date

01/04/2005

Eligibility

Key inclusion criteria

1. Psoriasis patients: plaque or guttata psoriasis
2. Eligible for total-body home UVB phototherapy based on the severity of the psoriatic skin lesions
3. Willing AND capable to participate in both possible treatment arms (treatment at home and in the hospital)
4. Sufficient knowledge of the dutch language
5. Age 18 years or more
6. Does have a telephone

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

196

Key exclusion criteria

1. Analphabetism
2. Expected non-compliance
3. History of malignancy of the skin
4. Known UVB allergy
5. Chronic polymorphic light eruption (CPLE)
6. Use of (systemic) medication with known phototoxic or photo-allergic properties
7. Use of the following systemic medication: cyclosporin (neoral), methotrexate, acitretin (neotigason)
8. History of ionising radiation

Date of first enrolment

01/10/2002

Date of final enrolment

01/04/2005

Locations**Countries of recruitment**

Netherlands

Study participating centre

University Medical Centre Utrecht (UMCU)

Utrecht

Netherlands

3508 GA

Sponsor information**Organisation**

University Medical Centre Utrecht (UMCU) (Netherlands)

Sponsor details

P.O. Box 85500

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3508 GA

Sponsor type

University/education

Website

<http://www.umcutrecht.nl/zorg/>

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2006		Yes	No
Results article	results	07/05/2009		Yes	No
Results article	results	20/04/2010		Yes	No