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A comparison of the clinical efficacies of Intense Pulsed Light (IPL), PhotoDynamic Therapy (PDT) and adapalene in the treatment of mild to moderate acne vulgaris

Submission date
07/04/2008

Recruitment status
No longer recruiting

Registration date
30/05/2008

Overall study status
Completed

Last Edited
19/05/2022

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
2008-000475-25

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
07/CMC/4136E

Study information

Scientific Title
Randomised, controlled, double-blind, parallel group clinical trial evaluating the efficacies and safety of methyl-aminolevulinate photodynamic therapy (PDT-MAL) and intense pulsed light, administered as placebo-photodynamic therapy (PDT-placebo), compared with the efficacy of adapalene 0.1% gel in the treatment of adults with mild to moderate acne vulgaris

Study objectives
Placebo photodynamic therapy (PDT) is at least as efficacious as adapalene 0.1% gel, and methyl-aminolevulinate (MAL)-PDT is more efficacious than either modality. MAL-PDT may also have a longer treatment-free period of acne remission.

On 11/02/2009 this record was updated to include amended trial dates. The initial trial dates at the time of registration were:
Initial anticipated start date: 01/06/2008
Initial anticipated end date: 01/06/2012

On 04/11/2009 this record was extensively updated. All updates can be found under the relevant field with the above update date. Please also note that the application regimen of MAL /placebo has been changed from 30 minutes without occlusion to 60 minutes with occlusion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitted to the South Wales Research Ethics Committee approval pending as of 11/02/2009

Study design
Double-blind parallel assignment randomised active controlled efficacy/safety study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Not available in web format, please contact project coordinator, Dr Chantal Suthananthan (details below), to request a patient information sheet

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

Interventions
Treatment schedule:
PDT-MAL arm: Full-face treatments every 2 weeks x 4
PDT-Placebo arm: Full-face treatments every 2 weeks x 4
Adapalene group: Participants instructed to use adapalene as monotherapy nightly

MAL cream (Metvix®):
For this research, we would like to achieve a good balance between efficacy, short treatment times and very minimal side-effects. Hence, short-contact (60 minutes) MAL cream will be used as the photosensitiser in this study.

Metvix® will be applied as a 1-mm film to the face, with occlusion, avoiding the areas immediately around the eyes, nose and lips. Patients will sit for 60 minutes in a darkened room. Prior to illumination, subjects will be asked to wash their faces using a gentle cleanser.

Placebo cream (Unguentum M®):
Unguentum M® is a cream containing liquid paraffin, white soft paraffin and saturated neutral oil. It also contains cetostearyl alcohol and glyceryl monostearate. Unguentum M® contains many of the excipients in Metvix®. 50 g tubes will be dispensed by the Pharmacy Department, University Hospital of Wales for patients within the placebo group at each visit. It will not be re-packaged. Application to the subject's face will be identical to MAL.

IPL Device Parameters:
Variable Pulsed Light is an IPL system that allows the operator to change the width, delay and number of the micropulses. The Energist ULTRAÔ VPLÔ System (Energist Ltd., UK) will be used for this study.

Device Settings: 530-950 nm cut-off filter; Double passes of: 20-40 J/cm2, 15 pulses, 5 ms duration, 20 ms delay (20 J/cm2, 15 x 5 x 20).

Adapalene gel (Differin® Gel 0.1% w/w):
Patients will be instructed to apply a thin film of adapalene gel to their faces, after washing it, nightly, avoiding the areas just around the eyes, nostrils and mouth. They will also be told and given written information about the possible side-effects in their patient information leaflets.

Added 04/11/09:
The number of visits will depend upon which arm of the research project the patient is involved in: the PDT group will make eight visits over 16 weeks and the adapalene group will make five visits over 16 weeks.

Treatment compliance:
Patients using adapalene will be reminded to apply their medication by methods such as weekly emails. On the assessment days, patients will be asked to bring their adapalene tubes, which will be weighed. The other treatments will be directly administered by the physician.

Concomitant treatment:
Sunblock lotion (SPF 30; Delph Lotion) will be provided by the department and should be used daily all over the face for the entire duration of the study.
An emollient (to be applied twice a day for a total of 5 days) will be given to all patients in the IPL groups post treatment.

Patients in the PDT-MAL and the PDT-placebo groups will also be asked to keep daily diary cards for the 44 weeks after the 4-month study period to document the time and severity of relapse and treatments used.

The follow-up period is 44 weeks beyond the end of the 16-week treatment period. The two follow-up appointments are at week 38 and 60

Project coordinator details
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Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Adapalene

Primary outcome measure
Current infomation as of 04/11/2009:
Lesion counts. The face will be divided into five areas. The types of lesions are classified as macules, comedones, papules, pustules, nodules and cysts. These will be counted in at least one of five possible facial cosmetic units before treatment. Subsequent lesion counts will be repeated in the chosen quadrant.

Outcomes will be measured at baseline, weeks 8, 11 and 16 in phase 1 (treatment phase) and weeks 38 and 60 for phase 2 (follow-up phase, PDT arms only).

Initial information at time of registration:
Lesion counts at baseline, Week 12 and 16, Month 7*, 10*, 13* and 16*.
*Follow-up for Months 7 to 16 applies only to the PDT arms.

Secondary outcome measures
Current information as of 04/11/2009:
1. Leeds Revised Acne Grading System scores measured at baseline, week 8, 11,16, 38 and 60
2. Seborrhoea measured using SM-815 sebumeter measured at baseline, week 8, 11,16, 38 and 60
3. P. acnes counts and culture measured at baseline, week 8, 11,16 and 60
4. P. acnes fluorescence photography measured at baseline, week 8, 11,16 and 60
5. Acne-specific Quality of Life Assessments (Acne QoL) measured at baseline, week 8, 11,16 and 60
6. Dermatology Life Quality Index (DLQI) measured at baseline, week 8, 11,16 and 60
7. The Family Dermatology Life Quality index (FDLQI) measured at baseline, week 16 and 60
8. Pain scores measured at day 1, week 3, 5, and 7
9. Subjective global assessment of acne improvement measured at baseline, week 8, 11 and 16

Initial information at time of registration:
1. Leeds Revised Acne Grading System scores at baseline, Week 12 and 16, Month 7*, 10*, 13* and 16*
2. Seborrhoea at baseline, Week 12 and 16, Month 7*, 10*, 13* and 16*
3. P. acnes counts at baseline and Week 7
4. P. acnes fluorescence photography. For all arms, this will be carried out at baseline, Weeks 7, 12 and 16, Months 7*, 10*, 13* and 16*
5. Dermatology Life Quality Index (DLQI) and/or Acne Quality of Life scale at baseline, Week 12 and 16
6. Pain scores (only in PDT-MAL and PDT-Placebo arms), assessed by a visual analogue scale (VAS) at Day 1 (Week 1), Week 3, 5 and 7
7. Subjective global assessment of acne improvement at baseline, Weeks 12 and 16

*Follow-up for Months 7 to 16 applies only to the PDT arms.

Overall study start date
01/01/2010

Completion date
13/08/2012

Eligibility

Key inclusion criteria
Current information as of 04/11/2009:
1. Aged 18 - 50 years, both males and females
2. Mild to moderate facial (face = area from hair line to jaw line) acne vulgaris with at least 15 inflammatory lesions and/or non-inflammatory lesions, but no more than three nodulocystic lesions. Thus, not exceeding Leeds grade 7.
3. Patients willing to have only their face treated
4. Skin phototypes IIII
5. Patients who are willing and able to provide written informed consent
6. Patients who agree to not use sun-beds or undergo any UV light treatment for 4 weeks prior to entering the study and are willing to minimise the amount of exposure to direct sunlight for

the duration of the study
7. Patients who have access to email accounts and are willing to reveal their email addresses to the study team

Initial information at time of registration
1. Aged 18 - 50 years, both males and females
2. Mild to moderate facial (face = area from hair line to jaw line) acne vulgaris with at least 15 inflammatory lesions and/or non-inflammatory lesions, but no more than three nodulocystic lesions. Thus, not exceeding Leeds grade 7.
3. Patients willing to have only their face treated
4. Skin phototypes IIII
5. Patients who are willing and able to provide written informed consent
6. Patients who agree to not use sun-beds or undergo any UV light treatment for 4 weeks prior to entering the study and are willing to minimise the amount of exposure to direct sunlight for the duration of the study
7. Patients who own a mobile phone and are willing to reveal their number to and receive text messages from the study team

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
120

Total final enrolment
37

Key exclusion criteria
Current information as of 04/11/2009:
1. Severe acne (>3 nodules and/or cysts present) or presence of scarring
2. Pregnancy and women contemplating pregnancy
3. Lactating females
4. Use of anti-androgen containing contraceptives
5. Mental incompetence
6. History of hypersensitivity to any of the study drugs or their excipients. i.e. adapalene, Metvix™ (e.g. peanut oil, soya), Unguentum M®.
7. Keloids or tendency to heal with keloids
8. Cosmetic treatment:
8.1. In the previous year with collagen, dermabrasion and laser resurfacing.

8.2. Alpha hydroxyl acids within 3 months
8.3. Microdermabrasion within 3 months
9. Photosensitivity disorders e.g. solar urticaria
9.1. Porphyrias or allergy to porphyrins
9.2. Epilepsy
10. Systemic retinoid use in the past 12 months
11. Use of Vitamin A supplements > 2000 IU /day
12. Oral antibiotics and topical retinoids for preceding 4 weeks
13. Systemic medications such as: steroids, immunosuppressant, statins and preparations containing St Johns wort
14. Oral photosensitisers within last 4 weeks (see Patient CRF)
15. Previous treatment with IPL or lasers to the areas of interest within the last 12 months
16. Severe systemic diseases such as: impaired renal or liver function; regional enteritis or ulcerative colitis; a history of antibiotic-associated colitis; severe cardiovascular, neurological disease, or any other disease that may interfere with the evaluation of the study medications
17. Patients with psoriasis, acne rosacea, allergic rashes, bacterial, viral or fungal infections of the facial skin, or other diseases of the facial skin
18. Patients with mild to moderate acne who have not tried over the counter treatment
19. Patients who are unlikely to be available for the duration of the follow-up
20. Persons involved in another clinical trial for the duration of this study
21. Persons who have another member of their household taking part in this study

Initial information at time of registration:
1. Severe acne (>2 nodules and/or cysts present) or presence of scarring
2. Pregnancy
3. Use of anti-androgen containing contraceptives
4. Mental incompetence
5. History of hypersensitivity to any of the study drugs or their excipients. i.e. adapalene, Metvix™ (e.g. peanut oil, soya), Unguentum M®
6. Keloids or tendency to heal with keloids
7. Cosmetic treatment:
7.1. In the previous year with collagen, dermabrasion and laser resurfacing
7.2. Alpha hydroxyl acids within the last month
7.3. Microdermabrasion within the last 3 months
8. Photosensitivity disorders e.g. solar urticaria
8.1. Porphyrias or allergy to porphyrins
8.2. Epilepsy
9. Systemic retinoid use in the past 12 months
10. Use of Vitamin A supplements >2000 IU /day
11. Oral antibiotics and topical retinoids for preceding 4 weeks
12. Systemic medications such as: steroids, immunosuppressant, statins and preparations containing St. John's wort
13. Oral photosensitisers within last 4 weeks
14. Previous treatment with intense pulsed light (IPL) or lasers to the areas of interest within the last 12 months
15. Severe systemic diseases such as: impaired renal or liver function; regional enteritis or ulcerative colitis; a history of antibiotic-associated colitis; severe cardiovascular, neurological disease, or any other disease that may interfere with the evaluation of the study medications
16. Patients with psoriasis, acne rosacea, allergic rashes, bacterial, viral or fungal infections of the facial skin, or other diseases of the facial skin

17. Patients who are unlikely to be available for the duration of the follow-up
18. Persons involved in another clinical trial for the duration of this study
19. Persons who have another member of their household taking part in this study

Date of first enrolment
01/01/2010

Date of final enrolment
01/06/2011

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Reader in Dermatology
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
Research and Commercial Development
30-36 Newport Road
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CF24 0DE

Sponsor type
University/education

Website
http://www.cardiff.ac.uk

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
University/education

Funder Name
Cardiff University (UK) - Department of Dermatology

Results and Publications

Publication and dissemination plan
Not provided at time of registration

2014 thesis in http://orca.cf.ac.uk/69644/

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		15/06/2019	19/05/2022	No	No