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Phase II, multi-centre, randomised, two-part pilot study (Part 1 open, uncontrolled; Part 2 double-blind, placebo controlled) to determine the efficacy, safety, tolerability and preliminary pharmacokinetics of PSD502 in the management of pain from donor sites in burns subjects undergoing skin grafts

Submission date
15/02/2007

Recruitment status
No longer recruiting

Registration date
20/04/2007

Overall study status
Completed

Last Edited
02/02/2017

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
PSD502-PM-001

Study information

Scientific Title
Phase II, multi-centre, randomised, two-part pilot study (Part 1 open, uncontrolled; Part 2 double-blind, placebo controlled) to determine the efficacy, safety, tolerability and preliminary pharmacokinetics of PSD502 in the management of pain from donor sites in burns subjects undergoing skin grafts

Study objectives
The aim of this study is to determine determining the efficacy of PSD502 in relieving the pain of skin graft donor sites in patients with severe burns, and the safety and tolerability of the preparation when applied to exposed dermal tissue.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Multi-centre REC, 01/02/2006, ref: 06/MRE06/8

Study design
Part 1: Uncontrolled open label study
Part 2 Double-blind placebo controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Management of pain from donor sites in burns subjects undergoing skin grafts.

Interventions

PSD502 is a metered dose aerosol spray that delivers a eutectic mixture of lidocaine and prilocaine. The placebo is a metered dose aerosol spray that is identical in appearance to the PSD502 spray and contains the same propellant.

Part 1:
Active PSD502 on one or both donor sites.

Part 2:
1. PSD502 and matching placebo on those subjects with paired donor sites (randomized and double-blind).
2. PSD502 or matching placebo on those subjects with one donor site.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Efficacy of PSD502 with placebo in relieving pain, as assessed by visual analogue pain scale (VAPS), from skin graft donor sites.

Secondary outcome measures
1. To evaluate the safety and tolerability of PSD502 applied to skin graft donor sites
2. To characterise the preliminary pharmacokinetics of PSD502
3. To evaluate and compare the effect of PSD502 with placebo on morphine requirements

Overall study start date
01/02/2006

Completion date
31/10/2007

Eligibility

Key inclusion criteria
1. Male or female ASA class I/II (American Society of Anesthesiologists class I or II) with burns that require skin grafts
2. Scheduled to have skin grafted from one or two donor sites.
3. Aged 18 - 75 years inclusive
4. Normal clinical examination (except for burns)
5. Able to understand and complete the VAPS form
6. Willing and able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
8 subjects in Part 1. 30 subjects in Part 2.

Key exclusion criteria
1. Skin grafted from three or more donor sites
2. Receipt of another investigational product within 3 months prior to screening
3. Known hypersensitivity to amide-type local anaesthetics, or other known drug allergies
4. Requirement for amide local anaesthetics pre- or intra-operatively. Should a subject receive amide local anaesthetics pre- or intra-operatively, they must be withdrawn
5. Clinically relevant abnormality on ECG, in the opinion of the investigator, such as prolonged QTc
6. History of alcohol or drug abuse
7. Clinically significant abnormal blood biochemistry or haematology, in the opinion of the investigator
8. History of psychiatric illness, from vulnerable groups, or have learning difficulties.
9. Female subjects who are pregnant or lactating
10. Sexually active females who are of child-bearing potential (<2 years post menopausal) and not using a reliable method of contraception (oral, injectable or implantable contraceptives, barrier methods of contraception, or surgically sterile)
11. Currently taking, or have taken within the 2 weeks prior to screening, any of the following medications: acetanilide, aniline dyes, benzocaine, chloroquine, dapsone, metoclopramide, naphthalene, nitrates (including glyceryl trinitrate), nitrites, nitroprusside, pamaquine, para-aminosalicylic acid, phenacetin, phenobarbital, phenytoin, primaquine, quinine, or sulfonamides
12. Have taken paracetamol within 2 hours of receiving study treatment
13. Known liver disease, known renal disease or heart failure

Additional Exclusion Criterion for Part 2:
14. Size of donor site(s) exceeds the area that can be covered by the maximum dose

Date of first enrolment
01/02/2006

Date of final enrolment
31/10/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

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Sponsor information

Organisation
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Sponsor type
Not defined

Website
http://www.plethorasolutions.co.uk/index.php

ROR
https://ror.org/02y9vw172

Funder(s)

Funder type
Industry

Funder Name
Plethora Solutions Limited (UK)

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