

An investigation of the efficacy of a single dose of insulin in the prevention of excessive cutaneous scarring in breast surgery patients

Submission date 03/08/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/08/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/01/2019	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10-0001

Study information

Scientific Title

An investigation of the efficacy of a single dose of insulin in the prevention of excessive cutaneous scarring in breast surgery patients: a phase II randomised controlled clinical trial

Acronym

IBBS

Study objectives

Treatment of non-cancer bilateral breast surgery wounds with a single low-dose application of insulin will improve the appearance of scarring as compared to that seen under standard care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled phase II clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Scarring in non-cancer bilateral breast surgery

Interventions

Administration by local injection of placebo (vehicle only) along the edge of a 3 cm length of one wound and 0.4 IU insulin to the other wound (randomised and double blinded) during surgery. Total duration of follow-up per patient is 12 months.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Insulin

Primary outcome measure

Severity of scar formation, as measured by standardised and accepted methods of scar tissue grading such as the Manchester Scar Scale, image analysis of digital photographs, and volumetric measurement of scar prominence using silicone moulds taken of the scars. Measured at 1 - 2 weeks and 3, 6 and 12 months.

Secondary outcome measures

Hypertrophic scars, measured at 1 - 2 weeks and 3, 6 and 12 months.

Overall study start date

31/10/2010

Completion date

31/10/2012

Eligibility

Key inclusion criteria

1. Female patients aged 18 - 60 years
2. Undergoing non-cancer related bilateral breast surgery - this patient group has been chosen for two reasons: Firstly they have two identical wounds allowing an ideal intra-patient placebo control since scarring severity varies markedly not only between individuals but also between body sites. Secondly these wounds have a high tendency towards formation of excessive scarring.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

75

Key exclusion criteria

1. Patients with diagnosed breast cancer
2. Patients with a history (either individual or familial) of keloid scarring (suspected to have a genetic component). Keloid scars are the most severe and pernicious form of pathological scarring that unlike hypertrophic scarring appear to behave in an almost cancer-like fashion

invading the surrounding non-wounded normal tissue. The causes of this form of scarring are likely to be more complex and potentially multi-factorial. In addition this particular condition is thought to have a genetic link and might therefore introduce extra variables which might complicate correct analysis of results.

3. Younger than 18 or older than 60 (The rate of wound healing is known to be different within these two age groups)

4. Smokers - impairs wound healing

5. Any systemic illness that could have a theoretical interaction with the insulin administered such as diabetics, patients with renal or liver disease or endocrine tumours

Exclusion criteria 2 - 4 are designed to eliminate extra variables which might complicate correct analysis of results. These criteria are largely theoretical as patients who do exhibit any of these features are unlikely to be put forward for non-cancer related breast surgery.

Date of first enrolment

31/10/2010

Date of final enrolment

31/10/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Queen Victoria Hospital NHS Foundation Trust

E Grinstead

United Kingdom

RH19 3DZ

Sponsor information

Organisation

Pharmecosse Ltd (UK)

Sponsor details

14 City Quay

Dundee

United Kingdom

DD1 3JA

Sponsor type

Industry

Website

<http://www.pharmecosse.com/>

ROR

<https://ror.org/011nmry48>

Funder(s)

Funder type

Industry

Funder Name

Pharmecosse Ltd (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018	17/01/2019	Yes	No