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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/08/2010	**Overall study status** Completed	
Last Edited 17/01/2019	**Condition category** Surgery	

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
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Hypertrophic scars, measured at 1 - 2 weeks and 3, 6 and 12 months.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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
United Kingdom

England

Study participating centre
Queen Victoria Hospital NHS Foundation Trust
E Grinstead
United Kingdom
RH19 3DZ

Sponsor information

Organisation
Pharmecosse Ltd (UK)

ROR
https://ror.org/011nmry48

Funder(s)

Funder type
Industry

Funder Name
Pharmecosse Ltd (UK)

Results and Publications

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				

Results article		01/04/2018	17/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes