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Study to evaluate the efficacy, safety and tolerability of pumactant 240mg in the prevention of the formation of peritoneal adhesions following abdominal surgery

Submission date 18/02/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2011	**Overall study status** Completed	
Last Edited 13/03/2014	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title
A randomised, partially double-blind, controlled, parallel group study to evaluate the efficacy, safety and tolerability of pumactant 240mg in the prevention of the formation of peritoneal adhesions following abdominal surgery

Study objectives
It is hypothesised that the application of pumactant powder into the abdominal cavity of human subjects following abdominal surgery may significantly reduce adhesion formation and potentially their associated morbidity. This trial was carried out to evaluate the efficacy of pumactant in reducing the formation of new peritoneal adhesions or the reformation of adhesions following abdominal surgery and its safety.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Tayside Committee on Medical Research Ethics, approved in February 2000.
At the time COREC identified Aberdeen Ethics committee as the Main REC (MREC) for this study. This was communicated and became effective from August 2004.

Study design
Randomised partially double-blind controlled parallel group multi-centre study

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
Post operative intraperitoneal adhesions

Interventions
On completion of the first surgical procedure for each subject, the peritoneum was cleansed and irrigated with saline. A single dose of pumactant powder 240 mg (comprising of 3 puffer devices administering 80 mg per device) was administered (according to the randomisation schedule) to

the peritoneal surface as an airborne dispersion immediately prior to closure. This was puffed onto the surface of the peritoneal cavity via carbon dioxide (CO2), using a puffer device, in as even strokes as possible so as to obtain a uniform covering.

For subjects randomised to receive CO2 alone (placebo), the identical puffer device was used but this was loaded with an empty vial (i.e. it administered only CO2 into the peritoneal cavity). After recovery from surgery, patients were readmitted 3-6 months later for reversal of colostomy / ileostomy. At that stage, adhesions were assessed and a further dose of pumactant (240 mg) or placebo was administered into the peritoneal cavity. After discharge from the second surgery, the patients involvement in the trial ceased.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
The evaluation of the efficacy of pumactant 240 mg in reducing the formation of peritoneal adhesions following abdominal surgery

Secondary outcome measures
Evaluate the safety and tolerability of pumactant 240 mg used in the peritoneal cavity following abdominal surgery

Overall study start date
01/04/2001

Completion date
01/07/2005

Eligibility

Key inclusion criteria
1. Male and female subjects (> 18 years old) were recruited into the study if it was thought that at the primary surgical procedure, they required the formation of a temporary stoma
2. Patients undergoing emergency treatment of obstructed /perforated carcinoma of the bowel or colonic diverticulitis by Hartmanns procedure
3. Patients undergoing elective low anterior bowel resection for the treatment of rectal carcinoma requiring formation of a temporary ileostomy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
140 (70 participants in each arm)

Key exclusion criteria
1. Patients unable to comply with the study requirements, had cognitive impairments, had a history of drug and / or alcohol abuse
2. Patients receiving steroid medication
3. Patients had metastatic disease
4. Patients had American Society of Anesthesiologists (ASA) fitness grade of IV or above
5. Pregnant or lactating females

Date of first enrolment
01/04/2001

Date of final enrolment
01/07/2005

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Surgery
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
Research and Innovation Service, University of Dundee (UK)

Sponsor details
University of Dundee
Nethergate
Dundee

Scotland
United Kingdom
DD1 4HN

Sponsor type
University/education

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Industry

Funder Name
Britannia Pharmaceuticals Limited, Surrey (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	01/12/2012		Yes	No