

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
Registration date 31/03/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 13/03/2014	Condition category Surgery	☐ 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

Protocol serial number

8

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

Scotland

Study participating centre**Department of Surgery**

Dundee

United Kingdom

DD1 9SY

Sponsor information

Organisation

Research and Innovation Service, University of Dundee (UK)

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Industry

Funder Name

Britannia Pharmaceuticals Limited, Surrey (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 article	results	01/12/2012		Yes	No