# 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	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
Registration date 31/03/2011	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 13/03/2014	<b>Condition category</b> Surgery	Individual participant data

**Plain English summary of protocol** Not provided at time of registration

## **Contact information**

**Type(s)** Scientific

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Contact details

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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?
<u>Results article</u>	results	01/12/2012		Yes	No