

Randomised double-blind, placebo-controlled multicentre trial of antioxidant therapy in painful chronic pancreatitis

Submission date 05/01/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/09/2012	Condition category Digestive System	<input type="checkbox"/> 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
01/06/57 version 9 (date: 21/12/2006)

Study information

Scientific Title

Acronym

Anticipate Trial

Study objectives

This study is designed to test the principal hypothesis that anti-oxidant therapy with ANTOX version 1.2 reduces pain in patients with painful chronic pancreatitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval will be submitted to the Local Ethical Committee (North West MREC) on the 13th February 2007 (Project No. 07/MRE08/13).

Study design

The study will take the form of a double-blind, placebo-controlled, multi-centre randomised trial of ANTOX version 1.2 in patients with painful chronic pancreatitis.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic pancreatitis

Interventions

We would be using intravenous blood sample for routine clinical Haematology/Bio-chemistry. Total dose of the treatment is two tablets three times a day for six months. Each tablet will be weighing 1145 mg (both Antox and placebo).

1. Pathological test: routine haematology and biochemistry
2. Face to face interview: with subjects enrolling in the trial

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Anti-oxidant therapy (ANTOX version 1.2)

Primary outcome(s)

Each patient enrolled in the study will contribute pain scores at baseline and six months from which a change in pain score will be calculated. The primary endpoint will be the difference in

change scores between treatment and control groups. The use of change rather than endpoint scores is important given the likely considerable interpersonal variation in the use of pain scales and thus removes interpersonal variance.

Key secondary outcome(s)

1. Time in pain assessed as the area under the curve of pain scores assessed at baseline, two, four and six months
2. Quality of life scores compared at enrolment to those at two, four and six months using disease specific measure (EORTC-QLQC30 and QLQ-PAN26) and a generic measure (EuroQOL EQ-5D)
3. Opiate usage (defined as morphine equivalents) assessed monthly over the six-month period of the study and analysed using repeated measures design
4. Incidence of specific pancreatitis-related complications: hospital admission with acute exacerbation of chronic pancreatitis or for pain control (defined from hospital discharge notes) and specific pancreatitis-related complications (pancreatic pseudocyst defined according to Atlanta consensus conference criteria) and pancreatic abscess
5. Economic analysis including use of anti-oxidant therapy and hospital-based resource utilisation associated with chronic pancreatitis
6. Assessment of any treatment-related side effects and complications

Completion date

31/08/2008

Eligibility

Key inclusion criteria

1. Ability to give informed consent
2. Age over 18 years
3. Computed Tomography (CT) within three months of trial enrolment
4. Either CT and/or Endoscopic Retrograde CholangioPancreatography (ERCP) or Magnetic Resonance (MR) evidence of chronic pancreatitis
5. CT and either ERCP or MR evidence to exclude pancreatic carcinoma with tests having been undertaken within three months of enrolment
6. Baseline median daily visual analogue pain score greater than five (on a ten point score) for at least seven days in a pre-randomisation run-in period of four weeks
7. Completion of daily visual analogue score-based pain diaries in the four week period preceding randomisation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Not meeting inclusion criteria
2. Inability to give informed consent
3. Inability to comply with trial protocol
4. Patients with chronic renal failure (with a creatinine clearance of less than 50 ml/minute)
5. Patients who are pregnant or lactating or who plan to become pregnant during the study period
6. Patients who are participating in another trial
7. Patients who are already taking antioxidants
8. Patients with schizophrenia

Date of first enrolment

01/02/2007

Date of final enrolment

31/08/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Surgery

Manchester

United Kingdom

M13 9WL

Sponsor information

Organisation

Pharmanord UK Ltd (UK)

ROR

<https://ror.org/00hz19x62>

Funder(s)

Funder type

Industry

Funder Name

Pharmanord UK 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 article	quality of life results	28/08/2010		Yes	No
Results article	results	01/09/2012		Yes	No