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

Submission date 05/01/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/01/2007	**Overall study status** Completed	
Last Edited 24/09/2012	**Condition category** Digestive System	

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).

Primary study design
Interventional

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.

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