

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

<b>Submission date</b> 05/01/2007	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/01/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/09/2012	<b>Condition category</b> 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).

**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?
<a href="#">Results article</a>	quality of life results	28/08/2010		Yes	No
<a href="#">Results article</a>	results	01/09/2012		Yes	No