

# Cisplatin Ototoxicity attenuated by ASpirin Trial (COAST)

<b>Submission date</b> 19/11/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/02/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-to-see-if-aspirin-can-reduce-hearing-loss-caused-by-cisplatin-coast>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

2012-001509-25

### IRAS number

### ClinicalTrials.gov number

## Secondary identifying numbers

13400

# Study information

## Scientific Title

A randomised, phase II, double-blind, placebo-controlled, two-arm trial to establish whether aspirin can reduce hearing loss/ototoxicity for patients receiving cisplatin chemotherapy

## Acronym

COAST

## Study objectives

The COAST study aims to recruit 88 cisplatin-naïve patients who will be undergoing high dose cisplatin treatment for malignancy in order to assess whether aspirin can reduce hearing loss in this group of patients. Approximately 18,500 patients receive Cisplatin on an annual basis within the UK and 50% of the patients receiving a high dose regimen have a significant reduction in hearing loss following treatment which is both permanent and irreversible. As Cisplatin is usually given with a curative intent the treatment potentially leaves a patient with resulting deafness that results in considerable reduction in Quality of Life. In some patients the hearing loss may be restored by use of hearing aids however in others the hearing loss is so severe that they could only be considered for cochlear implantation. As well as the impact on the quality of life of the patient both hearing aids and cochlear implantation have important short and long term costs to the NHS. The outcome of this research could therefore have important implications both economically and for the quality of life of cancer patients worldwide.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

First MREC, 20/08/2012 ref: 12/SC/0391

## Study design

Randomised interventional treatment trial

## 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 to request a patient information sheet

**Health condition(s) or problem(s) studied**

Cancer

**Interventions**

1. Aspirin & omeprazole: aspirin 975mg TID, omeprazole 20mg OD
2. Aspirin & omeprazole placebos: matching placebos to IMP

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Aspirin, omeprazole

**Primary outcome measure**

The total difference in hearing measured before and 7 days after treatment

**Secondary outcome measures**

1. Assessment of compliance and concomitant medications measured during entire study duration
2. Assessment of other PTA test-frequencies measured at 7 days post treatment and 3 months post treatment
3. Cisplatin dose-intensity measured during entire study duration
4. Common Toxicity Criteria (CTC) measured during entire study duration
5. OAE profile measured 7 days after finishing treatment and a further 3 months after finishing treatment
5. Safety profile assessment measured during entire study duration
6. The total difference in hearing measured before and 3 months after treatment

**Overall study start date**

31/10/2012

**Completion date**

29/12/2015

**Eligibility****Key inclusion criteria**

1. Written informed consent
2. Any patient deemed fit for chemotherapy with acceptable laboratory values and offered a cumulative dose equal to or more than 200mg/m<sup>2</sup> Cisplatin as a single agent or as a combination chemotherapy for malignancy with planned treatment of a maximum of two consecutive days Cisplatin per cycle
3. Over 18 years old
4. Male or female

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

UK Sample Size: 88; Description: We have estimated the SD of hearing loss (SD=45) from a sample of 27 people who have been treated with Cisplatin.

**Key exclusion criteria**

1. Previous cisplatin treatment
2. Patients with a diagnosis of Nasopharyngeal (or skull base) Carcinoma
3. Patients where planned Cisplatin is to be given as a split dose regimen on Days 1 to 5 or on Days 1 and 8
4. Patients receiving therapeutic Aspirin defined as >75mg per day
5. Previous transient ischaemic attacks or cerebral vascular disease
6. Severe ischaemic heart disease or myocardial infarction in the previous 6 months
7. Inflammatory bowel disease
8. Patients with absolute contraindications to Aspirin, PPIs or their excipients i.e. allergies, ulcers, renal impairment or use of oral anticoagulants
9. Haematological or clotting disorders
10. Patients with pre-existing sensorineural hearing loss (>40dB at the standard audiometric frequencies (0.5 8 inclusive) in their worst hearing ear)
11. Pregnant or breastfeeding patients. Women of childbearing potential must have a standard negative pregnancy test performed within 7 days prior to the start of Trial drug. Both men and women enrolled in this Trial must use adequate birth control
12. Patients enrolled or who plan to enrol in any other IMP or Surgical Interventional Clinical Trial during the Trial period

**Date of first enrolment**

31/10/2012

**Date of final enrolment**

31/10/2014

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Southampton University Hospitals NHS Trust**  
Southampton  
United Kingdom  
SO16 6YD

## **Sponsor information**

### **Organisation**

Southampton University Hospitals NHS Trust (UK)

### **Sponsor details**

Tremona Road  
Southampton  
England  
United Kingdom  
SO16 6YD

### **Sponsor type**

Hospital/treatment centre

### **Website**

<http://www.uhs.nhs.uk/>

### **ROR**

<https://ror.org/0485axj58>

## **Funder(s)**

### **Funder type**

Charity

### **Funder Name**

Cancer Research UK

### **Alternative Name(s)**

CR\_UK, Cancer Research UK - London, CRUK

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Other non-profit organizations

### **Location**

## Results and Publications

### Publication and dissemination plan

Once approved by Ethics, a letter to patients will be sent to all participating sites. They will then have the opportunity of sending it out to patients if applicable. Further publications are to be confirmed at a later date.

### Intention to publish date

### Individual participant data (IPD) sharing plan

There are no plans to make COAST participant level data available. Any request will need to be sent to the Southampton Clinical Trials Unit Data Release Committee (DRC) and will need to be agreed by both the DRC and Trial Management Group. The data will be held securely by Southampton Clinical Trials unit, maintained in a form that meets business needs and current regulatory requirement and destroyed after the retention period ends.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No