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Cisplatin Ototoxicity attenuated by ASpirin Trial (COAST)

Submission date	Recruitment status	[_] Prospectively registered
19/11/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/11/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/02/2018	Cancer	

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

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Additional identifiers

Clinical Trials Information System (CTIS)
2012-001509-25

Protocol serial number
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

Study type(s)
Treatment

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

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

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Aspirin, omeprazole

Primary outcome(s)
The total difference in hearing measured before and 7 days after treatment

Key secondary outcome(s))
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

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/m2 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 7days 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
United Kingdom

England

Study participating centre
Southampton University Hospitals NHS Trust
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (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, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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?
Results article	results	01/12/2017		Yes	No
HRA research summary			28/06/2023	No	No