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Study of aromatase inhibitors in women with potentially hormone responsive recurrent /metastatic gynaecological cancers

Submission date 22/12/2011	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 12/01/2012	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 29/10/2020	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-anastrozole-hormone-receptor-positive-gynaecological-cancers-paragon

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ANZGOG0903

Study information

Scientific Title
Phase II study of Aromatase inhibitors in women with potentially hormone Responsive recurrent /metastatic Gynaecological Neoplasms (PARaGoN)

Acronym
PARaGoN

Study objectives
Objective:
Determine clinical benefit rate by the proportion of patients experiencing either stable disease or response within 3 months of commencing treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Newcastle & North Tyneside, 07 December 2011 ref: 11/NE/0214

Study design
Single arm prospective phase II study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Hormone responsive recurrent/metastatic gynaecological neoplasms

Interventions
Patients will be eligible for the trial if they have hormone responsive recurrent /metastatic gynaecological cancer which is unlikely to be cured by standard treatment. To be considered for the trial the original tumour specimens will be re examined to ensure that they express the oestrogen receptor.

Patient will give written informed consent before enrollment, following enrollment all patients will be given a standard dose of the oral aromatase inhibitor anastrazole of 1mg per day. Patients will stay on treatment until progression or until 5 years after enrollment, whichever is the sooner.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Clinical benefit rate determined by the proportion of patients experiencing either stable disease or response within 3 months of commencing treatment. This will be determined radiologically by RECIST v1.1 or CA125 of inhibin (depending on the specific tumour type).

Secondary outcome measures
Progression free survival: this will be determined radiologically by Response Evaluation Criteria in Solid tumours (RECIST v1.1) or CA125 tumour marker response or inhibin.
1. Response duration in each subgroup: this will be determined radiologically by RECIST v1.1 or CA125 or inhibin.
2. Quality of life (QOL): will be assessed in the study using EORTC QLQ-C30 core questionnaire and the Functional Assessment of Cancer Therapy Endocrine Symptoms subscale.
3.Toxicity :Proportion of patients experiencing grade 3 or 4 toxicities, adverse events will be graded according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v4.0.

Overall study start date
01/01/2011

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Patient with recurrent or metastatic gynaecological cancer. The specific subgroups are outlined below. All patients will have central review and analyses of oestrogen receptor /progesterone receptor (ER/PR) at a later date to confirm receptor status but entry to the study will be based on local hormone receptor analyses.
1.1. Epithelial ovarian cancer, primary peritoneal cancers and cancers of the fallopian fube
1.2. Endometrial cancer: patients that have measurable disease
1.3. Endometrial stromal sarcomas: patients that have measurable disease
1.4. Miscellaneous sarcomas: includes leimyosarcomas, adenosarcomas, carcinoasrcomas and undifferentiated sarcomas which have relapsed following standard treatment such as chemotherapy or patients in whom chemotherapy is not considered appropriate.
1.5. Granulosa cell tumours and other sex cord tumours: patients with measurable disease and /or elevated inhibin (total inhibin and/or inhibin B? level
1.6. UK centres will only enter patients to subgroups B-E of the study
2. All patients must have ER and/or PR positive tumours by immunohistochemical evaluation based on the assessment at individual sites. Hormone receptor staining should be carried out on

the original tumour. If not available, but the recurrent tumour is receptor positive, then these patients will be eligible.
3. Post menopausal as defined by:
3.1. Aged 60 or more, or
3.2. Age 45-59 and has amenorrhoea for at least 12 months and follicle-stimulating hormone (FSH) in postmenopausal range with an intact uterus, or having had a bilateral oophorectomy
4. Evaluable disease defined as
4.1. Measurable disease as per Response Evaluation Criteria In Solid Tumours (RECIST) v1.1, or
4.2. Cancer antigen 125 (CA125) as per GCIG criteria (for ovarian cancer subgroup) or
4.3. Elevated total inhibin and/or inhibin B (for granulosa cell sub-group)
5. Eastern Cooperative Oncology Group (ECOG) peformance status 0-2
6. Expected survival > 3 months

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
350

Key exclusion criteria
Prior therapy with an aromatase inhibitor:
1. Patients receiving any hormone replacement therapy
2. Inability to comply with study procedures
3. Unable to give informed consent
4. Other active malignancy or primary malignancy diagnosed within the previous 5 years, except for treated squamous or basal cell carcinoma of skin or cervical carcinoma
5. Significant hepatic (bilirubin >2xULN) or renal dysfunction (creatinine>3x ULN)

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Northern Institute for Cancer Research
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
Research and Development
The Tennent Institute
Western Infirmary
38 Church Street
Glasgow
Scotland
United Kingdom
G11 6NT

Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK) ref: A12846

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Plain English results			29/10/2020	No	Yes
HRA research summary			28/06/2023	No	No