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The MAGENTA trial: The molecular biology of metastatic cancer

Submission date	Recruitment status	[ ] Prospectively registered
23/12/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/12/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/09/2016	Cancer	[ ] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-find-why-cancer-treatment-stops-working-magenta

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17675

Study information

Scientific Title
MAGENTA: Metabonomic-genomic signature correlates of clinical resistance in metastatic cancer treated with anti-EGFR therapy

Acronym
MAGENTA

Study objectives
The aim of this study is to investigate the clinical resistance in metastatic cancer treated with anti-EGFR therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Queen Square Research Ethics Committee, 02/12/2014, ref: 14/LO/1650

Study design
Non-randomised clinical laboratory study

Primary study design
Observational

Secondary study design

Study setting(s)
Other

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
Topic: Cancer; Subtopic: Colorectal Cancer, Head and Neck Cancer, Lung Cancer; Disease: Colon, Head and Neck, Lung (small cell), Lung (non-small cell), Skin

Interventions
Patients presenting to the Cancer Centre will receive an information sheet broadly describing research into the molecular biology of metastatic cancer. It will be made clear to patients that clinical information will be coded and linked to the molecular information. Patients with mCRC undergoing treatment with EGFR inhibitors will be the test sample population with an initial aim of 30-50 patients. There will also be a control group of non-EGFR treated patients (RAS- mutant or otherwise) of a minimum of 20 patients. Archival tumour tissue will be collected at baseline with an optional tissue biopsy at disease progression. 2-3 weekly collections of blood and urine will take place. A second control group will consist of 10 patients with any metastatic cancer receiving EGFR inhibitor therapy.

Intervention Type

Other

Primary outcome measure
The identification and validation of potential biomarkers in the form of specific differences in metastatis

Secondary outcome measures
Not provided at time of registration

Overall study start date
02/12/2014

Completion date
06/03/2017

Eligibility

Key inclusion criteria
1. -Histologically or cytologically confirmed colorectal cancer; or
2. Histologically or cytological confirmed lung, squamous cell, or head and neck cancers (only 10 patients required)
3. To commence EGFR inhibitor monotherapy or in combination with cytotoxic chemotherapy for the test populationb or to commence any other cytotoxic chemotherapy with or without an angiogenesis inhibitor for the control population
5. Confirmation of tumour KRAS / NRAS status as KRAS / NRAS WT in the test population, with mutation assessments in BRAF, NRAS, PIK3CA exon20 , PTEN if assessable, by means of mutation or relevant analysis performed on representative samples of diagnostic tumour tissue (the same profile will be done in controls with no pre-requisite mutation specified entry criteria)
-6. Ability to provide informed consent
-7. 18 years of age or older
8. ECOG performance status of = 2
-9. Life expectancy of at least 12 weeks
10. Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 70; UK Sample Size: 70

Key exclusion criteria
1. Brain metastases that are either untreated, symptomatic, or which have not been stable for at least one month after treatment
2. Severe restrictive lung disease or radiological pulmonary findings of “interstitial lung disease” on the CT scan image available prior to commencement of the treatment which, in the opinion of the investigator, represents significant pathology
3. Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule, including alcohol dependence or drug abuse
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5. Known human immunodeficiency virus (HIV) infection
6. Presence of grade =2 peripheral neuropathy.
7. Severe or uncontrolled cardiovascular disease (e.g. acute coronary syndromes, cardiac failure NYHA III or IV, clinically relevant myopathy, history of myocardial infarction within the last 12 months, significant arrhythmias)
8. Any co--morbididty that is likely to lead with interference with study treatment

Date of first enrolment
02/12/2014

Date of final enrolment
06/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Imperial College London

Sponsor details
Joint Research Compliance Office
Charing Cross Hospital
Fulham Palace Road
London
England
United Kingdom
W6 8RF

Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research organisation

Funder Name
Experimental Cancer Medicine Centre Network

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?

HRA research summary	28/06/2023	No	No