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

Contact name

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Contact details

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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 population 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?