

The MAGENTA trial: The molecular biology of metastatic cancer

Submission date 23/12/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/09/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

The identification and validation of potential biomarkers in the form of specific differences in metastasis

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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--morbidity 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

United Kingdom

England

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

ROR

<https://ror.org/041kmwe10>

Funder(s)

Funder type

Research organisation

Funder Name

Experimental Cancer Medicine Centre Network

Results and Publications

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