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Surgery versus no surgery of residual disease in patients with metastatic gastro-intestinal stromal tumour

Submission date 29/04/2010	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/04/2010	**Overall study status** Stopped	
Last Edited 04/08/2017	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-surgery-imatinib-gastrointestinal-stromal-tumours

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2007-002257-23

IRAS number

ClinicalTrials.gov number
NCT00956072

Secondary identifying numbers
7150

Study information

Scientific Title
A phase III randomised study evaluating surgery of residual disease in patients with metastatic gastro-intestinal stromal tumor responding to Imatinib mesylate

Acronym
EORTC 62063

Study objectives
The two principle objectives for this study are as follows:
1. To evaluate if surgery of residual disease in patients with advanced gastro-intestinal stromal tumour (GIST) responding to imatinib improves the progression free survival
2. To correlate the pharmacokinetics of imatinib and its metabolites in both arms with the pharmacokinetics of imatinib and its metabolites before randomisation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Manchester REC on 04/082009 (ref: 09/H1008/90)

Study design
Randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Sarcoma; Disease: Soft Tissue

Interventions
Eligible patients will be randomised after 6 to 12 months from starting imatinib for metastatic disease, to surgery of residual disease (investigational arm) or not. Patients allocated to the investigational arm will be operated within the 12th month from imatinib onset. Post-operative imatinib treatment will be restored as soon as possible after surgery. Patients allocated to the standard arm will continue imatinib treatment according to standard practice. In both arms,

patients will be followed for disease progression and/or discontinuation of imatinib therapy whenever that may be. Thereafter, patients will be followed for survival.

Intervention Type
Mixed

Primary outcome measure
Progression free survival (PFS), measured from the date of randomisation for surgery

Secondary outcome measures
Overall survival (OS) from the time of randomisation to death

Overall study start date
28/10/2009

Completion date
01/05/2015

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Histologically confirmed GIST expressing CD117+, or with documented mutation of the KIT or PDGFRA gene
2. Metastatic disease (liver and/or abdominal cavity); no extra-abdominal metastases
3. Treatment with imatinib administered for 6 - 12 months, resulting in complete remission (CR), partial remission (PR) or stable disease (SD), without progressive disease (PD) since the start of imatinib therapy (Response Evaluation Criteria in Solid Tumours [RECIST])
4. Measurable disease (RECIST) before start of imatinib
5. Surgically resectable residual disease (assessed on computed tomography [CT] scan/magnetic resonance imaging [MRI])
6. Aged greater than or equal to 18 years (either sex)
7. World Health Organization (WHO) performance status 0 to 1
8. Adequate haematological and organ function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 350

Key exclusion criteria
No prior treatment with imatinib or other tyrosine kinase inhibitors (for any reason) in the adjuvant or neoadjuvant setting

Date of first enrolment
28/10/2009

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
Australia

England

France

Germany

Italy

Netherlands

New Zealand

Spain

United Kingdom

Study participating centre
550 Wilmslow Road
Manchester
United Kingdom
M20 4BX

Sponsor information

Organisation
European Organisation for Research and Treatment of Cancer (EORTC) (Belgium)

Sponsor details

Avenue Mounierlaan, 83/11
Brussels
Belgium
1200

Sponsor type
Research organisation

Website
http://www.eortc.be/

ROR
https://ror.org/034wxcc35

Funder(s)

Funder type
Research organisation

Funder Name
European Organisation for Research and Treatment of Cancer

Alternative Name(s)
EORTC

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Belgium

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