

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

<b>Submission date</b> 29/04/2010	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2010	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/08/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-surgery-imatinib-gastrointestinal-stromal-tumours>

## Contact information

### Type(s)

Scientific

### Contact name

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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?
<a href="#">HRA research summary</a>			28/06/2023	No	No