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STI571 Prospective International RandomIsed Trial 2: A phase III, prospective randomised comparison of imatinib (STI571, Glivec®/ Gleevec®) 400 mg daily versus dasatinib (Sprycel®) 100 mg daily in patients with newly-diagnosed chronic phase chronic myeloid leukaemia

Submission date 17/04/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/10/2008	**Overall study status** Completed	
Last Edited 20/03/2020	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-imatinib-and-dasatinib-for-newly-diagnosed-chronic-myeloid-leukaemia

Study website
http://www.spirit-cml.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2007-006185-15

IRAS number

ClinicalTrials.gov number
NCT01460693

Secondary identifying numbers
4443

Study information

Scientific Title
STI571 Prospective International RandomIsed Trial 2: A phase III, prospective randomised comparison of imatinib (STI571, Glivec®/ Gleevec®) 400 mg daily versus dasatinib (Sprycel®) 100 mg daily in patients with newly-diagnosed chronic phase chronic myeloid leukaemia

Acronym
SPIRIT 2

Study objectives
To compare 5-year Event Free Survival (EFS) between the treatment arms. The study is powered to demonstrate superiority of the dasatinib arm over the imatinib arm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Research Ethics Committee in 11/2007 (ref: 07/H0718/90)

Study design
Phase III, multicentre, open-label, prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Newly diagnosed, chronic-phase, chronic myeloid leukaemia

Interventions
Arm 1: Imatinib (oral) 400 mg daily, to be taken for a minimum of 5 years
Arm 2: Dasatinib (oral) 100 mg daily, to be taken for a minimum of 5 years

All endpoints will be assessed at regular timepoints throughout the trial for a minimum of 5 years per patient.

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Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
STI571 (Glivec®/ Gleevec®) and dasatinib (Sprycel®).

Primary outcome measure
Event -free survival at 5 years

Secondary outcome measures
1. To compare the rate of complete cytogenetic response after 2 years
2. To compare the treatment failure rates (TFR) at 5 years
3. To compare the rates of complete haematologic response (CHR). Duration of follow-up: 60 months
4. To compare the level of 'molecular' response (BCR-ABL/ABL ratio by real time polymerase chain reaction [PCR]). Duration of follow-up: 60 months
5. To compare the tolerability between the regimens. This will in part be incorporated into the treatment failure assessment. Duration of follow-up: 60 months
6. To assess quality of life by the EQ-5D and the Functional Assessment of Cancer Treatment-Biological Response Modifier (FACT-BRM) questionnaires. Timepoints of assessment: at

screening and then Months 1, 2, 3, 6, 12, 24, 36, 48, 60
7. To assess the broad comparative costs between the regimens
8. To compare overall survival at 2 and 5 years

Overall study start date
30/06/2008

Completion date
30/06/2016

Eligibility

Key inclusion criteria
1. Male or female patients >= 18 years of age
2. Patients must have all of the following:
2.1. Be enrolled within 3 months of initial diagnosis of chronic myeloid leukaemia - chronic phase (CML-CP) (date of initial diagnosis is the date of first cytogenetic analysis)
2.2. Cytogenetic confirmation of the Philadelphia chromosome or variants of (9;22) translocations; patients may have secondary chromosomal abnormalities in addition to the Philadelphia chromosome
2.3. <15% blasts in peripheral blood and bone marrow
2.4. <30% blasts plus promyelocytes in peripheral blood and bone marrow
2.5. <20% basophils in peripheral blood
2.6. >= 100 x 10^9/L platelets
2.7. No evidence of extramedullary leukaemic involvement, with the exception of hepatosplenomegaly
3. Written voluntary informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
810

Key exclusion criteria
1. Patients with Ph-negative, BCR-ABL-positive disease are not eligible for the study
2. Any prior treatment for CML with: any tyrosine kinase inhibitor (e.g., imatinib, dasatinib, nilotinib); busulphan; interferon-alpha; homoharringtonine; cytosine arabinoside; any other investigational agents (hydroxycarbamide and anagrelide are the only drugs permitted). NB: Patients will be ineligible for the study if they have received any prior therapy with interferon-alpha or imatinib. No exceptions.

3. Patients who received prior chemotherapy, including regimens used in peripheral blood progenitor cells (PBPCs) mobilisation for haematopoietic progenitor-cell transplantation (It is allowable to collect unmobilised PBPCs at diagnosis)
4. Patient who have had any form of prior haemopoietic stem cell transplant, either autograft or allograft
5. Patients with an Eastern Cooperative Oncology Group (ECOG) Performance Status Score >= 3
6. Patients with serum bilirubin, aspartate aminotransferase (SGOT/AST), alanine aminotransferase (SGPT/ALT), or creatinine concentrations > 2.0 x the institutional upper limit of the normal range
(IULN)
7. Patients with International normalised ratio (INR) or partial thromboplastin time (PTT) >1.5 x IULN, with the exception of patients on treatment with oral anticoagulants
8. Patients with uncontrolled medical disease such as diabetes mellitus, thyroid dysfunction, neuropsychiatric disorders, infection, angina, or Grade 3/4 cardiac problems as defined by the New York Heart Association Criteria
9. Patients with known positivity for human immunodeficiency virus (HIV); baseline testing for HIV is not required
10. Patients who have undergone major surgery within 4 weeks of Study Day 1, or who have not recovered from prior major surgery
11. Patients who are:
11.1 Pregnant
11.2. Breast feeding
11.3. Of childbearing potential without a negative pregnancy test prior to Study Day 1
11.4. Male or female of childbearing potential unwilling to use barrier contraceptive (Amenorrhoeic for at least 12 months to be considered of non-childbearing potential)
12. Patients with a history of another malignancy either currently or within the past five years, with the exception of basal cell skin carcinoma or cervical carcinoma in situ
13. Patients with a history of non-compliance to medical regimens or who are considered potentially unreliable

Date of first enrolment
30/06/2008

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle-upon-Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
R&D Department
4th Floor
Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
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NE1 4LP

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Industry

Funder Name
Bristol Myers-Squibb (USA)

Alternative Name(s)
Bristol-Myers Squibb Company, BMS

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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?
Basic results				No	No
Results article	results	12/07/2012	10/04/2019	Yes	No
Results article	results	04/04/2013	10/04/2019	Yes	No