A phase III, prospective randomised comparison of imatinib (STI571, Glivec/Gleevec) 400 mg daily versus imatinib 800 mg daily versus imatinib plus PEG interferon-alpha 2a (Pegasys) in patients with newly-diagnosed chronic phasechronic myeloid leukaemia

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered			
18/05/2001		<pre>Protocol</pre>			
Registration date	Overall study status Completed	Statistical analysis plan			
18/05/2001		[X] Results			
Last Edited	Condition category	Individual participant data			
16/05/2019	Cancer				

Plain English summary of protocol

http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-different-doses-of-glivec-for-chronic-myeloid-leukaemia-with-or-without-interferon

Contact information

Type(s)

Scientific

Contact name

Dr Stephen G O'Brien

Contact details

Department of Haematology
University of Newcastle upon Tyne
Royal Victoria Infirmary
Newcastle upon Tyne
United Kingdom
NE1 4LP
+44 (0)191 282 0605
s.g.o'brien@ncl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)

2004-001622-24

Protocol serial number

G0100059

Study information

Scientific Title

A phase III, prospective randomised comparison of imatinib (STI571, Glivec/Gleevec) 400 mg daily versus imatinib 800 mg daily versus imatinib plus PEG interferon-alpha 2a (Pegasys) in patients with newly-diagnosed chronic phasechronic myeloid leukaemia

Acronym

SPIRIT

Study objectives

The only known curative therapy for Chronic Myeloid Leukaemia (CML) is allogeneic Stem Cell Transplantation (SCT) but the risks of this are considerable and it is only available to a minority of patients with CML. Imatinib (ST1571, Gleevec, Glivec) has produced remarkable results in the treatment of CML although data on long term survival are not available.

In light of recent evidence, National Institute for Clinical Excellence (NICE) have recommended imatinib as the standard of care for newly diagnosed CML patients (http://www.nice.org.uk /Docref.asp?d=89864). SPIRIT aims to establish whether combining imatinib with other drugs, or increasing the dose to 800 mg daily can improve survival when compared to imatinib 400 mg daily. This is a crucial long-term study attempting to improve the survival for patients with CML and to determine the optimal non-transplant therapy for CML.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The London main REC gave a favourable opinion for the trial on the 20th August 2004 (ref: O4 /MREC02/13). Each participating site has gained Site Specific Assessment (SSA) approval from their local ethics committee prior to patient recruitment at that site.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic Myeloid Leukaemia

Interventions

Arm A: Imatinib 400 mg daily for the duration of the study Arm B: imatinib 800 mg daily for the duration of the study

Arm C: imatinib 400 mg daily plus weekly PEG interferon-alpha 2a for the duration of the study

Patients will be followed up for at least 10 years post study via the National Office of Statistics.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Imatinib (STI571, Glivec/Gleevec), PEG interferon-alpha 2a

Primary outcome(s)

To compare overall survival in the three arms at five years

Key secondary outcome(s))

- 1. To compare molecular response at one year
- 2. Treatment tolerability after 5 years
- 3. health economics after 5 years
- 4. Quality of life after 5 years

Completion date

01/01/2015

Eligibility

Key inclusion criteria

- 1. Male or female patients 18 years or older
- 2. Patients must have all of the following:
- a. Be enrolled within three months of initial diagnosis of CML-CP (date of initial diagnosis is the date of first cytogenetic analysis)
- b. Be previously untreated for CML with the exception of hydroxyurea and/or anagrelide
- c. Cytogenetic confirmation of the Philadelphia chromosome or variants of (9;22) translocations, patients may have secondary chromosomal abnormalities in addition to the Philadelphia chromosome
- d. Less than 15% blasts in peripheral blood and bone marrow
- e. Less than 30% blasts plus promyelocytes in peripheral blood and bone marrow
- f. Less than 20% basophils in peripheral blood
- g. More than or equal to 100×10^9 l platelets
- h. No evidence of extramedullary leukaemic involvement, with the exception of the hepatosplenomegaly
- 3. Written voluntary informed consent

Participant type(s)

Patient

Healthy volunteers allowed

Age group

Adult

Lower age limit

18 years

Sex

All

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 busulphan, interferon-alpha, imatinib, homoharringtonine, cytosine arabinoside, or any other investigational agents (hydroxyurea and anagrelide are the only drugs permitted)
- N.B. patients will be ineligible for SPIRIT if they have received ANY prior therapy with interferonalpha or imatinib. NO exceptions
- 3. Patients who received prior chemotherapy, including regimens used in Peripheral Blood Progenitor Cells (PBPCs) mobilization for haematopoietic progenitor-cell transplantation. It is allowable to collect unmobilized PBPCs at diagnosis
- 4. Patients who have had any form of prior haemopoietic stem cell transplant, eitherautograft or allograft
- 5. Patients with an Eastern Cooperative Oncology Group (ECOG) Performance Status Score more than or equal to three
- 6. Patients with serum bilirubin, Serum Glutamic Oxaloacetic Transaminase (SGOT)/aspartate aminotransferase (AST), Serum Glutamic Pyruvic Transaminase (SGPT)/alanine aminotransferase (ALT), or creatinine concentrations more than 2.0 x the Institutional Upper Limit of the Normal range (IULN)
- 7. Patients with International Normalised Ratio (INR) or Partial Thromboplastin Time (PTT) more than 1.5 x IULN, with the exception of patients on treatment with oralanticoagulants
- 8. Patients with uncontrolled medical disease such as diabetes mellitus, thyroid dysfunction, neuropsychiatric disorders, infection, angina, or Grade three/four cardiac problems as defined by the New York Heart Association Criteria
- 9. Patients with a prior history of significant psychiatric illness, particularly depression
- 10. Patients with known positivity for Human Immunodeficiency Virus (HIV); baseline testing for HIV is not required
- 11. Patients who have undergone major surgery within four weeks of Study Day one, or who have not recovered from prior major surgery
- 12. Patients who are:
- a. Pregnant
- b. Breast feeding
- c. Of childbearing potential without a negative pregnancy test prior to Study Day one
- d. Male or female of childbearing potential unwilling to use barrier contraceptive precautions throughout the trial (postmenopausal women must be amenorrheic for at least 12 months to be considered of non-childbearing potential)
- 13. 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
- 14. Patients with a history of non-compliance to medical regimens or who are considered potentially unreliable

Date of first enrolment 03/06/2005

Date of final enrolment 01/01/2015

Locations

Countries of recruitmentUnited Kingdom

orneed rangeon

England

Study participating centre
Department of Haematology
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation

Newcastle upon Tyne Hospitals Trust (UK)

ROR

https://ror.org/05p40t847

Funder(s)

Funder type

Industry

Funder Name

Novartis Pharma AG (Switzerland)

Funder Name

Roche Pharmaceuticals (Switzerland)

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?
Basic results			16/05/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes