A Multicenter Phase 3 Randomized, Open-Label Study of Bosutinib Versus Imatinib in Adult Patients With Newly Diagnosed Chronic Phase (CP) Chronic Myelogenous Leukemia (CML)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25517

Source
Nationaal Trial Register

Brief title
BFORE study

Health condition

Leukemia, Myelogenous, Chronic, Breakpoint Cluster Region-Abelson Proto-oncogene (BCR-ABL) Positive

Sponsors and support

Primary sponsor: Avillion Development 1 Limited
Source(s) of monetary or material Support: Avillion Development 1 Limited

Intervention

Outcome measures

Primary outcome

Compare proportion of participants with Major Molecular Response (MMR) at 12 Months in the bosutinib arm with that of the imatinib arm [Time Frame: 12 Months] [Designated as safety issue: No]

MMR is defined as <0.1%Bcr-Abl1 on the International Scale (IS) by Real Time Quantitative Polymerase Chain Reaction (RT-PCR)

Secondary outcome

• Compare proportion of participants with MMR at 18 Months in the bosutinib treatment group with the imatinib treatment group [Time Frame: 18 Months] [Designated as safety issue: No]

• To determine the duration of MMR in the bosutinib treatment group with the imatinib treatment group [Time Frame: 5 Years] [Designated as safety issue: No]

Duration of MMR is measured only for participants who initially respond to study medication.

• To determine the proportion of participants with Complete Cytogenetic Response (CCyR) by 12 Months in both treatment groups [Time Frame: 12 Months] [Designated as safety issue: No]
CCyR is defined as absence of detectable Ph chromosomes in bone marrow aspirate

• To determine the duration of CCyR in both treatment groups [Time Frame: 5 Years] [Designated as safety issue: No]

Duration of response is measured only for participants who initially respond to study medication.

Study description

Study objective

To compare proportion of participants with Major Molecular Response (MMR) at 12 Months in the bosutinib arm with that of the imatinib arm

Study design

12 Months

18 Months

5 Years

See outcomes

Intervention

The study will be open for enrollment until the planned number of approximately 500 Philadelphia Chromosome Positive (Ph+) patients have been randomized (approximately 250 Ph+ patients in each treatment arm; a total of approximately 530 Ph+ and Ph- patients). All patients will be treated and/or followed for 5 years (240 weeks) after randomization until the study has closed. Patients who discontinue study therapy early due to disease progression or intolerance to study medication will continue to be followed yearly for survival for up to 5 years (240 weeks) after randomization.

Contacts

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Eligibility criteria

Inclusion criteria

1. Molecular diagnosis of CP CML of < 6 months (from initial diagnosis)

2. Adequate hepatic, renal and pancreatic function

3. Age > 18 years

Exclusion criteria

1. Any prior medical treatment for CML, including tyrosine kinase inhibitors (TKIs), with the exception of hydroxyurea and/or anagrelide treatment.

2. Any past or current Central Nervous System (CNS) involvement, including leptomeningeal leukemia.

3. Extramedullary disease only.

4. Major surgery or radiotherapy within 14 days of randomization.

5. History of clinically significant or uncontrolled cardiac disease.

6. Known seropositivity to human immunodeficiency virus (HIV), current acute or chronic hepatitis B (hepatitis B surface-antigen positive), hepatitis C or evidence of decompensated liver disease or cirrhosis.

7. Recent or ongoing clinically significant GI disorder, e.g. Crohn's Disease, Ulcerative Colitis, or prior total or partial gastrectomy.

8. History of another malignancy within 5 years with the exception of basal cell carcinoma or cervical carcinoma in situ or stage 1 or 2 cancer that is considered adequately treated and currently in complete remission for at least l2 months.

9. Current, or recent (within 6 months), participation in other clinical trials.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2014
Enrollment:	530
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-10-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4723
NTR-old	NTR4868
Other	NL48355.029.14 : NCT02130557

Study results