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)

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25517

Bron
Nationaal Trial Register

Verkorte titel
BFORE study

Aandoening

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

Ondersteuning

Primaire sponsor: Avillion Development 1 Limited
Overige ondersteuning: Avillion Development 1 Limited

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Doel van het onderzoek

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

Onderzoeksopzet

12 Months

18 Months

5 Years

See outcomes

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

VU University Medical Center
De Boelelaan 1117
J.J.W.M. Janssen
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4442604

Wetenschappelijk

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The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. Adequate hepatic, renal and pancreatic function

3. Age > 18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	530
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-10-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten