A single-arm, international, multi-center trial of HuMax-CD20, a fully human monoclonal anti-CD20 antibody, in patients with B-cell Chronic Lymphocytic Leukemia who have failed fludarabine and alemtuzumab

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Primary: To evaluate the efficacy and safety of HuMax-CD20 in patients with B-cell Chronic Lymphocytic Leukemia (B-CLL) who have failed fludarabine and alemtuzumabSecondary: To determine the host immune response to HuMax-CD20To determine the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lymphomas non-Hodgkin's B-cell
Study type	Interventional

Summary

ID

NL-OMON30130

Source
ToetsingOnline

Brief title
HuMax-CD20 in B-CLL patients failing fludarabine and alemtuzumab

Condition

- Lymphomas non-Hodgkin's B-cell

Synonym
Blood Cancer, Chronic Lymphocytic Leukemia (B-CLL)

Research involving

Human

Sponsors and support

Primary sponsor: Genmab
Source(s) of monetary or material Support: vierde geldstroom (derde geldstroom is nvt)

Intervention

Keyword: Chronic Lymphocytic Leukemia

Outcome measures

Primary outcome

Objective response as measured over a 24 week period from start of treatment assessed by an Independent endpoints Review Committee (IRC) according to the NCIWG guidelines

Secondary outcome

Duration of response, Progression Free Survival (PFS), Time to next B-CLL therapy, Overall survival, Reduction in tumor size, CD5+CD19+, CD5+CD20+ in peripheral blood, and expressions of CD19, CD20, CD55 and CD59 on CD45+CD5+ cells, Constitutional symptoms (B-symtoms), Resolution of lymphadenopathy, Resolution of organomegaly,

Prognostic value of FISH-parameters, CD38+, VH mutational status, FC receptor polymorphisms, C1qA-276 mutation, β2 microglobulin, thymidin kinase, circulating CD20, antigen density,

Improvement in ECOG Performance Status, Improvement in hemoglobin, Improvement in thrombocytopenia, Improvement in neutropenia, Number of blood transfusions,

Number of grade 3 and 4 infections, Number of autoimmune hemolysis

Study description

Background summary

Patients failing fludarbine and alemtuzumab have currently no available treatments options. HuMax CD20 is a fully human antibody which might meet this unmet medical need.

Study objective

Primary:
To evaluate the efficacy and safety of HuMax-CD20 in patients with B-cell Chronic Lymphocytic Leukemia (B-CLL) who have failed fludarabine and alemtuzumab

Secondary:
To determine the host immune response to HuMax-CD20
To determine the pharmacokinetic profile of HuMax-CD20

Study design

international, multicenter, signle-arm, open

Intervention

Each patient will receive eight weekly infusions of HuMax-CD20, followed by 4 monthly infusions of HuMax-CD20.

Study burden and risks

At screening, different blood samples, a physical examination, a CT scan and a bone marrow examination are done and the patient is evaluated for eligibility in the trial.
Disease status will be assessed every 4 weeks until Week 28, including physical examination, spleen and liver measurement, and blood samples.
A CT scan and a bone marrow examination will be performed for confirmation 8 weeks after a patient, for the first time, fulfills the NCIWG requirements of a CR.
After Week 28, disease status evaluation (physical examination, spleen and liver measurement, and blood samples) will take place every 3 months until disease progression or until Month 24.
Hereafter, the patients will be monitored for CD5-CD19+ and CD5-CD20+ cells

until one value >= the baseline value or until alternative B-CLL treatment or Month 48. Patients will be followed for survival at 3-months intervals until Month 48.
The evaluation of response will be done centrally by an IRC. Evaluation of response will be done at Visit 6 and from Visit 10 to 21.

In regard to burden and risks does this trials have no difference than the patient would have with other treatment such as for example Rituximab.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The trial population will be comprised of patients with a diagnosis of B-CLL who have failed both fludarabine and alemtuzumab and who have active disease.;Active B-CLL is defined and

confirmed according to the NCIWG guidelines and with an indication for treatment.;Failing at least one fludarabine-containing treatment regimen is defined as:
1. Refractory to one fludarabine -containing treatment regimen, defined as:
a. failure to achieve at least PR to at least one fludarabine-containing treatment regimen; or,
b. disease progression while on a fludarabine-containing treatment regimen; or,
c. disease progression in responders within 6 months of the last dose of a fludarabine-containing treatment regimen;2. Intolerant to fludarabine, defined as:
a. Discontinuation of therapy due to side effects/toxicity whether or not response occurred; or
b. Ineligible to treatment with fludarabine due to history of previous fludarabine-induced autoimmune hemolytic anemia or autoimmune thrombocytopenia;Failing at least one alemtuzumab-containing treatment regimen is defined as:
1. Refractory to one alemtuzumab-containing treatment regimen, defined as:
a. failure to achieve at least PR to at least one alemtuzumab-containing treatment regimen; or,
b. disease progression while on a alemtuzumab-containing treatment regimen; or,
c. disease progression in responders within 6 months of the last dose of a alemtuzumab-containing treatment regimen
2. Intolerant to alemtuzumab, defined as:
a. Discontinuation of therapy due to side effects/toxicity whether or not response occurred; or,
b. Ineligible to treatment with alemtuzumab due to concurrent medical conditions, such as:
i. previous pneumocystis carinii pneumonia (PCP) ii. history of other severe opportunistic infections iii. repeated grade 3 or 4 infections of other types
iv. lympadenopathy with at least one lymph node > 5 cm causing symptoms or compression and requiring therapy;A patient must have failed at least one fludarabine-containing treatment regimen and one alemtuzumab-containing treatment regimen, as defined above. Patients must have an ECOG Performance Status of 0, 1 or 2 and a life expectancy of at least 4 months.;The patients should be >= 18 years of age and have given informed consent.

Exclusion criteria

The most important exclusion criteria consist of previous treatment with alemtuzumab within 6 weeks prior to Visit 1, previous autologous stem cell transplantation within 6 months prior to Visit 1, allogenic stem cell transplantation at any time, radioimmunotherapy at any time or anticancer therapy within 4 weeks prior to Visit 1 and known or suspected transformation of B-CLL.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2006
Enrollment:	3
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	HuMax-CD20
Generic name:	ofatumumab

Ethics review

Approved WMO Date:	27-06-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-10-2006
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-12-2006
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	14-12-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-05-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-09-2007
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-05-2008
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2005-006163-31-NL

Register	ID
CCMO	NL11928.078.06