Target to B! - Towards patient-tailored immunotherapy to effectively treat B-cell associated disease

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To characterize the antibody and the immune cell compartment in B-cell-related disease in different states of disease activity. Study objectives fall within two main groups: 1) to compare antibodies to self or non-self-antigens before and after...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49992

Source
ToetsingOnline

Brief title
T2B!

Condition

- Other condition
- Autoimmune disorders

Synonym
B-cell related disorders; B-cell mediated immunological or oncological disorders

Health condition

hematologische aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Health~Holland,AcertaPharma,Janssen-Cilag,Pfizer

Intervention

Keyword: B-cells, cohort, immunology

Outcome measures

Primary outcome

The primary outcome will be (changes in) titer of IgG antibodies, or if

appropriate, titer of IgM antibodies.

Secondary outcome

Secondary outcomes will include: antibody characteristics, cellular and

clinical parameters.

Study description

Background summary

B-cells are an essential arm of adaptive immunity by generating protective memory and anti-bodies. When out of balance, aberrant B-cell differentiation and escape from immunological checkpoints may lead in B-cell-related immune-mediated or oncological diseases. Traditional-ly, research on B-cell-related diseases has been confined to these specific syndromes, which is extremely challenging considering the low prevalence of most these disorders separately. The aim of this study is to support the prospective collection of standardized clinical data and biosamples in a selected group of diseases to allow for standardized comparison of the im-munological signature between B-cell-related diseases and during different phases of disease activity.

Study objective

To characterize the antibody and the immune cell compartment in B-cell-related disease in different states of disease activity. Study objectives fall within two main groups: 1) to compare antibodies to self or non-self-antigens before

and after immunosuppressive or immunomodu-lating treatment and 2) to explore B-cell characteristics.

Study design

Explorative, prospective multicenter observational cohort study.

Study burden and risks

Participation in this study has negligible risk because the only intervention done is venapunc-ture to obtain blood. In principal, study visits will be planned to coincide with standard clinical visits to decrease the burden for participants. There is no direct benefit for participants. Re-sults from this project may help to increase therapy-outcome and reduce side-effects by providing mechanistic and prognostic understanding why some patients/patient-groups re-spond well, whereas others do not. This study can only be done in this population to capture the full diversity of human B-cell-related disease.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

1) subjects with a clinical syndrome fulfilling the diagnostic criteria for pre-specified B-cell-related diseases; 2) disease severity requiring start of anti-CD20 or antibody targeted therapy and 3) adults or children above the age of 5 years.

Exclusion criteria

1) anti-CD20 treatment or thymectomy as part of clinical care, within the last 9 months ; 2) plasma exchange, plasmapheresis or immunoadsorption within the last 3 months ; 3) change in the dose of general immunosuppressive or oncological drugs, including azathioprine, mycophenolate mofetil, ciclosporin, tacrolimus within the last 3 months (change in dose of corticosteroids or intravenous immunoglobulin dose allowed); 4) anti-CD20 treatment or antibody depleting therapy as part of clinical trials as based on case-based peer review between researchers

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-09-2020
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO Date:	31-03-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL72179.018.19