# Dendritic cell and B cell response to Campylobacter predisposing to Guillain-Barré syndrome.

Published: 04-10-2010 Last updated: 04-05-2024

The primary objective is to determine whether the DC/B-cell response to C. jejuni LOS differs in (ex-)patients with C. jejuni-related GBS compared to healthy controls. Secondly, we aim to define the variation in DC/B-cell response to C. jejuni LOS...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Observational invasive

# Summary

### ID

NL-OMON34577

**Source** ToetsingOnline

**Brief title** DC/B response in GBS

### Condition

• Peripheral neuropathies

# **Synonym** acute inflammatory demyelinating polyneuropathy, no lay-term

### **Research involving**

Human

## **Sponsors and support**

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam Source(s) of monetary or material Support: Stichting Spieren voor Spieren

### Intervention

Keyword: Campylobacter jejuni, Dendritic cells, Guillain-Barré syndrome, Immune response

#### **Outcome measures**

#### **Primary outcome**

The DC response to LOS as determined by: 1) B-cell proliferative capacity; 2)

production of cytokines, including interferon (IFN)-β, interleukin (IL)-6,

IL-10, IL-12 and tumor necrosis factor (TNF)- $\alpha$ ; and 3) expression of

differentiation markers, including CD40, CD80, CD86 and HLA-DR.

#### Secondary outcome

Gene expression profile of DC stimulated with C. jejuni LOS of (ex-)GBS

patients and healthy controls.

# **Study description**

#### **Background summary**

Campylobacter jejuni is the predominant preceding infection in Guillain-Barré syndrome (GBS) and is associated with severe weakness and poor prognosis. Molecular mimicry between C. jejuni lipo-oligosaccharides (LOS) and gangliosides induces cross-reactive antibody responses precipitating peripheral nerve damage. This aberrant immune response after C. jejuni infection only occurs in a minority of susceptible persons. Dendritic cells (DC) are known to orchestrate the immune response to infection. In recent pilot studies we found that DC and B-cell responses to C. jejuni LOS differ significantly between persons. High responders may be at risk to develop GBS after C. jejuni LOS defines the constitutional susceptibility to develop GBS after C. jejuni infection.

#### **Study objective**

The primary objective is to determine whether the DC/B-cell response to C. jejuni LOS differs in (ex-)patients with C. jejuni-related GBS compared to healthy controls. Secondly, we aim to define the variation in DC/B-cell

response to C. jejuni LOS in healthy controls. Finally, using gene expression profiles we will define the crucial DC molecules that determine a high DC/B-cell response to C. jejuni LOS.

#### Study design

Cross-sectional observational cohort study and longitudinal observational cohort study

#### Study burden and risks

Subjects will be asked to visit the Outpatient clinic neurology. Blood will be drawn to isolate white blood cells and to isolate DNA. These samples will be obtained in less than 10 minutes and carry negligible risks. The identification of host factors that cause GBS will be of benefit to future patients, since persons could be identified with a high risk of developing GBS after C. jejuni infection. This is important for epidemiological studies in GBS and for excluding persons in vaccination studies for C. jejuni. In addition, understanding the activation of DC by C. jejuni may provide a rationale to develop new treatments that interfere with the early immune response, preventing the subsequent activation of B cells. This approach will add to current therapeutic strategies that target the effector phase of the disease, such as IVIg, plasmapheresis and complement inhibitors.

# Contacts

#### Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 50 3015 GE Rotterdam NL **Scientific** Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 50 3015 GE Rotterdam NL

# **Trial sites**

## **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

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

### **Inclusion criteria**

Healthy controls (partners, non-related family members or friends of the (ex)-GBS patients):

- Age 18 years or older

- Written informed consent given by the subject.

Ex-GBS patients:

- Fulfilling the diagnostic criteria for GBS (Asbury, 1990)
- Culture-proven and/or positive serology for C. jejuni (at time of diagnosis).
- Current age: 18 years or older
- Diagnosis of GBS was made after 1987 and at least one year before inclusion in the study.
- Patients were treated at the ward of the department of Neurology, Erasmus MC, or at the Sophia Children\*s Hospital.

- Written informed consent was given by the subject.

### **Exclusion criteria**

Both groups:

- Additional diseases or disorders at the time of diagnosis or at time of blood sampling that may influence the endpoints:

\*autoimmune diseases (like multiple sclerosis, psoriasis, Crohn\*s disease, ulcerative colitis, hepatitis, rheumatoid arthritis, SLE and other systemic diseases)

\*acute and chronic infectious diseases (like infectious mononucleosis, HIV/AIDS)

\*malignancies (not in remission);- Medicines at time of blood sampling that may affect endpoints (i.e. inflammatory processes):

\*NSAIDs, corticosteroids, cyclosporine

\*Cytostatic compounds

\*Cytokines (analogues) and biologicals

\*Intravenous immunoglobulins.

# 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:	Recruitment stopped
Start date (anticipated):	01-05-2011
Enrollment:	60
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	04-10-2010
Application type:	First submission
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

ССМО

ID NL33335.078.10