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Change ID issued by UMIN-CTR	UMIN000039888
Receipt number	113475
Study ID	Safety and efficacy of tocilizumab in patients with neuromyelitis optica
Date of disclosure of the study information	2017-Year-07-Month-28-Day
Last modified on	2017-07-19-Day

This page includes information about the registered UMIN-clinical trial registry system
*The text and or numbers marked with * are required*

Public title

The safety and efficacy of tocilizumab in patients with neuromyelitis optica

Acronym

Tocilizumab in patients with neuromyelitis optica

Scientific Title

The safety and efficacy of tocilizumab in patients with neuromyelitis optica

Scientific Title.Acronym

Tocilizumab in patients with neuromyelitis optica

Region

Japan

Condition

neuromyelitis optica

Classification by specialty

Neurology

Classification by malignancy

Others

Genomic information

NO

Narrative objectives1

The purpose of this study is to evaluate safety and efficacy of anti-IL6R antibody tocilizumab in intractable neuromyelitis optica and to explore mechanism underlying its effectiveness.

Basic objectives2

Safety/Efficacy

Basic objectives -Others

Trial characteristics_1

Confirmatory

Trial characteristics_2

Exploratory

Developmental phase

Not applicable

Primary outcomes

An improvement in MRI lesions, relapsing rate, and EDSS at baseline and 6 months thereafter.

Key secondary outcomes

Study type

Interventional

Basic design

Single arm

Randomization

Non-randomized

Randomization unit

Blinding

Open (no one is blinded

Control

Uncontrolled

Stratification

Dynamic allocation

Institution consideration

Blocking

Concealment

No. of arms

1

Purpose of intervention

Treatment

Type of intervention

Medicine

Interventions/Control_1

Tocilizumab is to be infused every 4 weeks at 8 mg/kg of body weight for 6 months.

Interventions/Control_2

Interventions/Control_3

Interventions/Control_4

Interventions/Control_5

Interventions/Control_6

Interventions/Control_7

Interventions/Control_8

Interventions/Control_9

Interventions/Control_10

Age-lower limit

20 years-old<=

Age-upper limit

65 years-old=<

Gender

Male and Female

Key inclusion criteria

Diagnosis of neuromyelitis optica (NMO), as defined by 2006 criteria published in NEUROLOGY vol.66 or NMO seronegative spectrum disorder (recurrent optic neuritis or longitudinally extensive transverse myelitis). All patients must be anti-aquaporin 4 antibody seropositive.

Patients with intractable NMO who are resistant to the standard therapy or experiencing severe adverse reactions of the current therapy.

Provision of written informed consent to participate in this study.

Key exclusion criteria

1) Patients with severe infection such as tuberculosis, pneumocystis carini pneumonia, nontuberculous mycobacterial infection, cryptococcosis, or invasive fungal infection.
2) Patients with a history of tuberculosis infection or patients with pleural thickness or calcification in chest X-ray.
3) Patients with a history of hypersensitivity to the drug.
4) Patients with a history of gastrointestinal perforation.
5) Patients with interstitial pneumonitis.
6) Patients with leukopenia (white blood cell number < 4000/mm3), lymphopenia (lymphocyte number < 1000/mm3) or seropositivity for human immunodeficiency virus.
7) Pregnant women or patients with possible pregnancy.
8) Patients who are not provide consent to participate in the study by themselves.
9) Patients whose ESR3 are more than 5.

Target sample size

3

Name of lead principal investigator

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Institute

Department

Personal name

Organization

Ministry of Health, Labour and Welfare

Organization

Division

Category of Funding Organization

Nationality of Funding Organization

Co-sponsor

Name of secondary funder(s)

Organization

Address

Tel

Email

Secondary IDs

NO

Study ID_1

Org. issuing International ID_1

Study ID_2

Org. issuing International ID_2

IND to MHLW

Institutions

Date of disclosure of the study information

2017-Year-07-Month-28-Day

URL releasing protocol

Publication of results

Partially published

URL related to results and publications

Number of participants that the trial has enrolled

Results

Results date posted

Results Delayed

Results Delay Reason

Date of the first journal publication of results

Baseline Characteristics

Participant flow

Adverse events

Outcome measures

Plan to share IPD

IPD sharing Plan description

Progress

Recruitment status

Completed

Date of protocol fixation

2011 Year 06 Month 30 Day

Date of IRB

Anticipated trial start date

2011 Year 07 Month 01 Day

Last follow-up date

2012 Year 10 Month 11 Day

Date of closure to data entry

2012 Year 10 Month 11 Day

Date trial data considered complete

2013 Year 03 Month 31 Day

Date analysis concluded

2013 Year 03 Month 31 Day

Other

Other related information

Management information

Registered date

2011 Year 06 Month 30 Day

Last modified on

2014 Year 11 Month 27 Day

Link to view the page

Value
https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000006933

Research Plan	
Registered date	File name

Research case data specifications	
Registered date	File name

Research case data	
Registered date	File name

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