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Recent updates	Recruiting
Trial number	UMIN000047896
Date of disclosure of the study information	2019-Sep-05
Last modified on	2019-09-05 12:00:41

* This page includes information about the registered / with-drawn trial regular system
* This page is in a provisional status with restricted access.

Public title

The safety and efficacy of tocilizumab in patients with neuromyelitis optica: Multicenter Study

Acronym

Tocilizumab in patients with neuromyelitis optica: Multicenter Study

Scientific Title

The safety and efficacy of tocilizumab in patients with neuromyelitis optica: Multicenter Study

Scientific Title.Acronym

Tocilizumab in patients with neuromyelitis optica: Multicenter Study

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 its mechanism of action.

Basic objectives2

Safety/Efficacy

Basic objectives -Others

Trial characteristics_1

Exploratory

Trial characteristics_2

Pragmatic

Developmental phase

Not applicable

Primary outcomes

Adverse events up to 2 years
MRI lesion parameters, relapsing rate, and EDSS up to 2 years

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: to be infused every 4 weeks at 8 mg/kg of body weight for 8 years.

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 spectrum-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.
History of at least one relapse during the 1 year prior to initiation of the study
Provision of written informed consent to participate in the study

Key exclusion criteria

1) Patients with severe infection such as tuberculosis, pneumocystis carini pneumonia, nontuberculous mycobacterial infection, cryptococcosis, and invasive fungal infection, etc.
2) Patients with a history of hepatitis infection or patients with abnormal thickness or old tuberculosis in chest X-ray
3) Patients with a history of hypersensitivity to this drug
4) Patients with active hepatitis or cirrhosis
5) Patients with interstitial pneumonitis
6) Patients with a history of malignancy (exclusion: UMSCHAD, lymphoma (lymphocyte number < 1000/mm3) or seropositivity for hepatitis B virus or periphral blood
7) Patients with a history of or possible pregnancy
8) Patients who can not provide consent to participate in the study by themselves.
9) Patients whose EDSS are more than 7.

Target sample size

15

Name of lead principal investigator

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Institute

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Institute

Department

Personal name

Organization

Ministry of Health, Labour and Welfare

Organization

Division

Category of Funding Organization

Japanese Governmental Office

Nationality of Funding Organization

Japan

Co-sponsor

Department of Neurology, Keio University Faculty of Medicine

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

2019-Sep-05-00:00:00 Day

URL releasing protocol

Publication of results

Unpublished

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

No longer recruiting

Date of protocol fixation

2011 Year 09 Month 30 Day

Date of IRB

Anticipated trial start date

2012 Year 05 Month 01 Day

Last follow-up date

Date of closure to data entry

Date trial data considered complete

Date analysis concluded

Other

Other related information

Management information

Registered date

2012 Year 04 Month 30 Day

Last modified on

2016 Year 06 Month 30 Day

Link to view the page

Value
https://center6.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000009239

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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