Delayed recovery from naturally infected upper respiratory tract infections by loxoprofen: a randomized controlled trial

Submission date	Recruitment status	Prospectively registered		
20/12/2005	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/01/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
25/09/2009	Respiratory			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Acronym

The Great Cold Study 2

Study objectives

Loxoprofen, one of the Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), prolongs the recovery process of naturally-infected upper respiratory tract infections

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethical Committee of Kyoto University Faculty of Medicine (No. 404, October 29, 2002)

Study design

Randomised double-blind placebo-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Upper Respiratory Tract Infection (URTI)

Interventions

Patients in the intervention group take loxoprofen sodium (60 mg/tablet) and those in the control group take a placebo similar to active loxoprofen

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Loxoprofen sodium

Primary outcome(s)

The interval, in days, from the onset of any URTI symptom to the disappearance of all URTI symptoms

Key secondary outcome(s))

Severity of the URTI symptoms

Completion date

31/03/2004

Eligibility

Key inclusion criteria

Patients aged 18 through to 65 years who exhibit symptoms or signs in both the nose and pharynx and have visited physicians within 48 hours after symptom onset

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Patients who were clinically supposed to suffer from influenza, pneumonia of any cause, β -streptococcus tonsillitis, and other bacterial infections
- 2. Patients with serious or confusing underlying diseases including: bronchial asthma, peptic ulcer, diabetes mellitus, and allergic rhinitis
- 3. Immunocompromized or pregnant persons
- 4. Patients who were currently using antibiotics, systemic corticosteroids, immunosuppressants or anticoagulants
- 5. Patients who had taken NSAIDs or Chinese herbal medicines as cold remedies within 12 hours

Date of first enrolment

01/12/2002

Date of final enrolment

31/03/2004

Locations

Countries of recruitment

Japan

Study participating centre Yoshida-Honmachi

Kyoto Japan 606-8501

Sponsor information

Organisation

Kyoto University (Japan)

ROR

https://ror.org/02kpeqv85

Funder(s)

Funder type

Charity

Funder Name

Suzuken Memorial Foundation (2002)

Funder Name

Uehara Memorial Foundation (2003)

Funder Name

Grant for Frontier Medicine from the Ministry of Education, Culture, Sports, Science and Technology, Japan (2002-2004)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2007		Yes	No