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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Severity of the URTI symptoms

Overall study start date
01/12/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
170

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
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Sponsor information

Organisation
Kyoto University (Japan)

Sponsor details
Yoshida-Honmachi
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Sponsor type
University/education

Website
http://www.kyoto-u.ac.jp/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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