ISRCTN60440500 https://doi.org/10.1186/ISRCTN60440500

Influcid® in Feverish Infections

Submission date 19/10/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/11/2010	**Overall study status** Completed	
Last Edited 11/08/2011	**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
09-NI-EP-001

Study information

Scientific Title
Efficacy, safety and tolerability of Influcid® tablets in patients (1 to 65 years old) suffering from upper respiratory tract infections with flu-like symptoms

Acronym
INFI

Study objectives
No formal study hyothesis has been formulated. The data will be analyzed exploratively The study has been set up to evaluate systematically the efficacy and tolerability of Influcid® when used in addition to standard symptomatic treatment in comparison to standard symptomatic treatment alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ukraine: The Central Ethics Commission of Ministry of Healthcare of Ukraine approved on the 16th of September 2010 (ref: 5.12-1109/KE)
2. Russian Federation: The Ethics Committee of Federal Service of Oversight in the Field of Healthcare and Social Development approved on the 25th of August 2010 (ref: 40232)

Added 10/11/10:
3. Germany: The Ethics Committee of the Bavarian State Medical Association (Ethikkommission der Bayrischen Landesärztekammer) approved on the 26th of October (ref: 10068)

Study design
Randomised international multicentre open controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact the sponsor (contact details see below) to request a patient information sheet

Health condition(s) or problem(s) studied
Patients suffering from upper respiratory tract infection

Interventions
Patients will be randomised to
1. Intervention group: Influcid® treatment starts immediately after the baseline visit and continues for seven days. There is no run-in period, where patients are monitored before they are receiving Influcid®.
2. Control group: Symptomatic medication only, no placebo.

All study patients (control-group as well as Influcid®-group) will receive symptomatic medication provided at the discretion of the investigator depending on the symptoms of the patient. Symptomatic medication can be administered throughout study duration.

Patients will be followed for 14 days in total.

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
1. Fever measurement
2. Symptom assessment via illness-specific quality of life questionnaire (WURSS-21)
Outcomes will be measured at day 4, day 8, and at the study termination visit.

Secondary outcome measures
1. Documentation of symptomatic medication intake
2. Assessment of impairment of daily activity
3. Treatment outcome according to Integrative Medicine Outcomes Scale (IMOS)
4. Satisfaction with treatment according to Integrative Medicine Patient Satisfaction Scale (IMPSS)
5. Tolerability
6. Adverse events
Outcomes will be measured at day 4, day 8, and at the study termination visit.

Overall study start date
15/11/2010

Completion date
30/04/2011

Eligibility

Key inclusion criteria
1. Subjects aged 1 to 65 years
2. Diagnosis of upper respiratory tract infection
3. Written informed consent
4. Willingness and ability to comply with all trial procedures

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
520

Key exclusion criteria
1. Severe or complicated course of the URTI
2. Signs of acute lower respiratory tract disease
3. Current symptoms mainly induced by other acute ENT (Ear-Nose-Throat) disease
4. Present chronic inflammatory ENT and respiratory tract disease
5. Obstructive anatomic lesions in the nasopharynx
6. Severe heart diseases, HIV-infection, unstable diabetes mellitus, coeliac disease and/or immunosuppression, tuberculosis and lues
7. Severe renal or hepatic dysfunction in past 12 months prior to enrolment
8. Children with congenital anomalies of heart, kidney or liver
9. Any significant alarm symptom within the past 6 months prior to enrolment
10. Evidence of any malignant disease during the past 5 years prior to enrolment
11. Galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption
12. Hypersensitivity to any of the ingredients and/or excipients of Influcid®
13. Hypersensitivity to any of the ingredients and/or excipients as well as any known contraindications to the symptomatic treatment defined in this protocol
14. Positive rapid test for group A £]-hemolytic streptococci (GABHS)
15. Treatment with antibiotics, glucocorticosteroids, immunomodulators, or antihistamines during the past 4 weeks prior to or at enrolment as well as current indication requiring these drugs during the trial
16. Indication for administration of or treatment with antiviral drugs
17. Treatment with any antipyretics, nasal decongestants, expectorants and/or any other cold medication or measure for relief of URTI e.g. local anesthetics, anti-inflammatory drugs, antitussiva, homeopathic drugs, nutritional supplements or drugs containing zinc, echinacea, garlic or vitamin C (d 100 mg per day), during the past 7 days prior to or at enrolment
18. Heavy smoking or known or suspected drug addiction
19. Inadequate contraception, pregnancy, lactation;
20. Participation in another clinical trial during the past 3 months prior to enrolment
21. Incompetence or incapability of understanding nature, meaning and consequences of the trial

Date of first enrolment
15/11/2010

Date of final enrolment
30/04/2011

Locations

Countries of recruitment
Germany

Russian Federation

Ukraine

Study participating centre
Fäustlestraße 3
München
Germany
80339

Sponsor information

Organisation
Deutsche Homöopathie-Union (DHU)-Arzneimittel GmbH & Co. KG (Germany)

Sponsor details
Ottostraße 24
Karlsruhe
Germany
76227

Sponsor type
Industry

ROR
https://ror.org/0451ek747

Funder(s)

Funder type
Industry

Funder Name
Deutsche Homöopathie-Union (DHU)-Arzneimittel GmbH & Co. KG (Germany)

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