Antivirals for influenza Like Illness? An rCt of Clinical and Cost effectiveness in primary CarE (ALICE)

Published: 17-11-2015
Last updated: 20-04-2024

ALICE is a randomised controlled trial in Primary Care that aims to determine whether adding antiviral treatment to best usual primary care is effective in reducing time to return to usual daily activity and so the clinical and cost effectiveness of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON45203

Source
ToetsingOnline

Brief title
ALICE

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
flu, Influenza-like illness

Research involving
Human

Sponsors and support

Primary sponsor: University of Oxford, contact person Prof. Christopher Butler
Source(s) of monetary or material Support: de Europese Unie (Funding Programme 7)

Intervention

Keyword: Antivirals, Influenza Like Illness, Primary care

Outcome measures

Primary outcome

To determine whether adding antiviral treatment to best usual primary care is effective in reducing time to return to usual daily activity.The outcome measured is 'Time to return to usual daily activity'.

Secondary outcome

To determine whether adding antiviral treatment to best usual primary care:

1. Is cost effective

2. Decreases the incidence of hospital admissions

3. Decreases complications related to influenza like illness (ILI), especially pneumonia

4. Decreases repeat attendance at the GP

5. Decreases time to alleviation of ILI symptoms

6. Decreases the incidence of new or worsening symptoms

7. Decreases time to initial reduction in severity of symptoms

8. Decreases duration of symptoms that are moderately severe or worse

9. Reduces the use of additional symptomatic and prescribed medication, including antibiotics

10. Reduces the transmission of infection within household

11. Affects the self-management of ILI symptoms

12. Benefits certain subgroups of patients more than others

Study description

Background summary

Title: Antivirals for influenza-Like Illness? An rCt of Clinical and Cost effectiveness in primary CarE (ALICE)

Given the findings of a reduction of 0.5 to 1 day in the time to first alleviation of symptoms from treatment of ILI (influenza-Like Illness) with antivirals, important questions remain:
Does this effect found in efficacy studies translate into meaningful benefit in every day primary care? Specifically, what are the overall costs and benefits of this shortened symptom duration from the perspective of the individual sufferer, for the health services, and for society? Or do patients considered to be at higher risk from complications of influenza (due to age or co-morbidity for example) receive additional benefit from antiviral treatment in primary care?

Answering these questions will reduce important clinical uncertainty for primary care clinicians about whether to prescribe antiviral agents for ILI.

Study objective

ALICE is a randomised controlled trial in Primary Care that aims to determine whether adding antiviral treatment to best usual primary care is effective in reducing time to return to usual daily activity and so the clinical and cost effectiveness of adding antiviral agents to best usual primary care of people suffering from influenza-like illness (ILI).

Study design

The ALICE trial is a open, prospective, international, non-industry sponsored, pragmatic randomised controlled trial in Primary Care. The trial will be executed in approximately 20 European primary care networks. An adaptive trial design will be used to test the study hypothesis.

Intervention

ALICE will be initiated with two open, intervention arms with patient assignment by remote randomisation:
1. Oseltamivir, in the recommended doses for children and adults, with best usual primary care
2. Best usual primary care

Those whom the responsible clinician considers should receive immediate

treatment with antiviral agents will not be eligible for the trial (this is one of the exclusion criteria).

Study burden and risks

All patients will complete a symptom diary for 2 weeks (this may take up to 5 minutes every day). At baseline patients aged <16 will have an oropharyngeal and nasal swab taken. Those >=16 will have a nasopharyngeal swab taken. Around day 3, day 14 and after one 1 month the patients will be contacted by telephone to complete a short questionnaire.
There are some common side effects when taking Oseltamivir, such as a headache and nausea. Some of the less common side effects include dizziness, fatigue , abdominal pain and insomnia.
There are no guaranteed benefits from taking part. However, this study aims to improve the treatment of flu-like illnesses in the future.

Contacts

Public
University of Oxford, contact person Prof. Christopher Butler

New Radcliffe House 2nd Floor, Radcliffe Observatory Quarter
Oxford OX1 6GG
GB
Scientific
University of Oxford, contact person Prof. Christopher Butler

New Radcliffe House 2nd Floor, Radcliffe Observatory Quarter
Oxford OX1 6GG
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

•Male or Female, aged at least one year;•Presenting with ILI* in primary care during a period of increased influenza activity.;* ILI=sudden onset of self-reported fever, with at least one respiratory symptom (cough, sore throat, running or congested nose) and one systematic symptom (headache, muscle ache, sweats or chills or tiredness), symptom duration of 72 hours or less;•Is able and willing to comply with all trial requirements;•Participant or legal guardian(s) of a child is willing and able to give informed consent ;•Agrees not to take antiviral agents apart from study antiviral agents according to patient randomisation

Exclusion criteria

The participant may not enter the trial if ANY of the following apply:;•Chronic renal failure e.g. known or estimated creatinine glomerular filtration rate < 60 ml/min (known = recorded in GP clinical records);•Condition or treatment associated with significant impaired immunity (e.g. long-term oral steroids, chemotherapy, or immune disorder) (known = recorded in GP clinical records);•Those who in the opinion of the responsible clinician should be prescribed immediate antiviral treatment;•Allergic to oseltamivir, or any other trial medication;•Scheduled elective surgery or other procedures requiring general anaesthesia during the subsequent two weeks;•Participant with life expectancy estimate by a clinician to be less than 6 months;•Patient with severe hepatic impairment ;•Responsible clinician considers urgent hospital admission is required ;•Any other significant disease or disorder which, in the opinion of the responsible clinician, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or may affect the participant*s ability to participate in the trial;•Involvement, including completion of any follow up procedures, in another clinical trial of an investigational medicinal product in the last 90 days;•Previous ALICE trial participation ;•Patients unable to be randomised within 72 hours after onset of symptoms;•Requirement for any live viral vaccine in the next 7 days

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2016
Enrollment:	135
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tamiflu 6 mg/ml powder for oral suspension
Generic name:	Oseltamivir 6 mg/ml powder for oral suspension
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Tamiflu 75 mg hard capsules
Generic name:	Oseltamivir 75 mg hard capsules
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	17-11-2015
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	23-12-2015
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	18-02-2016

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-11-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-12-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-01-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-10-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-01-2018
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2014-004471-23-NL
CCMO	NL54143.041.15

Study results

Results posted: 08-09-2020

First publication
04-01-2020