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Effects of inhaled hypertonic saline in children with cystic fibrosis

Submission date
04/05/2016

Recruitment status
No longer recruiting

Registration date
06/07/2016

Overall study status
Completed

Last Edited
19/10/2017

Condition category
Genetic Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cystic fibrosis (CF) is an inherited condition which causes the lungs and digestive system to become blocked with mucus. It is caused by a faulty gene, which is responsible for controlling the movement of water and salts in and out of cells. This leads to a buildup of sticky mucus which clogs the lungs and airways causing breathing difficulties and lung infections, and the digestive system which affects the way food travels through and the ability to absorb nutrients from it. Most people with CF experience problems with lung function and usually are treated with a combination of physiotherapy and medications to prevent lung infections and the buildup of mucus that causes damage. Bronchodilator medications are commonly used in the treatment of CF, as they make breathing easier by relaxing the muscles in the lungs and widening the airways. Following bronchodilation, patients are often given normal saline (salt water) through a nebulizer in order to bring up the mucus blocking their lungs. The aim of this study is to investigate the effectiveness and safety of using hypertonic saline (a solution which is more concentrated than in the body) in children with CF.

Who can participate?
Preschool aged children with cystic fibrosis being treated using bronchodilators and physiotherapy.

What does the study involve?
Participants are randomly allocated to one of two groups who receive two treatments for 16 weeks in a different order. The first treatment involves inhaling a mist of 4ml normal saline (salt water), twice a day for 16 weeks. The second treatment involves inhaling a mist of 4ml hypertonic (more concentrated than blood) saline, twice a day for 16 weeks. At the start of the study and then again after 4, 16, 20 and 32 weeks, participants in both groups complete a number of breathing tests (involving breathing into a machine in various ways) in order to measure how well their lungs are working. Throughout the study, any side effects experienced by the children are recorded on a questionnaire.

What are the possible benefits and risks of participating?
There is a possibility that participants may benefit from improved breathing and lung function. There are no notable risks involved with taking part in this study,

Where is the study run from?
Sapienza University of Rome (Italy)

When is the study starting and how long is it expected to run for?
February 2010 to February 2015

Who is funding the study?
Policlinico Umberto I (Italy)

Who is the main contact?
Dr Rafaella Nenna

Contact information

Type(s)
Scientific

Contact name
Dr Raffaella Nenna

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01

Study information

Scientific Title
Effects of inhaled hypertonic (7%) saline on lung function test in preschool children with cystic fibrosis: a crossover, randomized clinical trial

Study objectives
The aim of this study is to evaluate whether inhaled hypertonic saline is effective and safe in children with cystic fibrosis.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Scientific Ethics Committee, Policlinico Umberto I, 11/03/2010, ref: HS-2009-Prot.1818(11/03/2010)

Study design
Double-blind randomised cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No specific participant information sheet available, please use the contact details below to request a further information.

Health condition(s) or problem(s) studied
Cystic fibrosis

Interventions
Participants are randomly allocated to one of two groups who receive two treatments in a random order.

Treatment 1: Participants receive inhalatory administration of 4ml hypertonic saline (HS - 7 % sodium chloride) twice daily for 16 weeks
Treatment 2: Participants receive inhalatory administration of 4ml normal saline (NS - 0.9 % sodium chloride) twice daily for 16 weeks

There is no washout period between the two treatments, and children are followed up after 4, 16, 20 and 32 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hypertonic saline

Primary outcome measure

1. Airways resistance was measured using interrupter resistance technique at baseline, 4, 16, 20, 32 weeks
2. FVC, FEV1 and FEF25-75 were measured using spirometry at baseline, 4, 16, 20, 32 weeks

Secondary outcome measures
Side effects were registered using a standardized questionnaire created for the purpose of this study throughout the 31 week study period by healthcare providers.

Overall study start date
01/02/2010

Completion date
01/02/2015

Eligibility

Key inclusion criteria
1. Children aged 4-6 years
2. Diagnosis of cystic fibrosis
3. Clinically stable
4. Undergoing a simple therapy based on bronchodilators and physiotherapy
5. No respiratory infections during the treatment or 2 weeks before

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
Children with instable medical conditions

Date of first enrolment
01/09/2012

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
Italy

Study participating centre
Sapienza University of Rome
Cystic Fibrosis Centre
Department of Pediatrics and Infantile Neuropsychiatry
V.le Regina Elena 324
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Sponsor information

Organisation
Sapienza University of Rome

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/02be6w209

Funder(s)

Funder type
University/education

Funder Name
Policlinico Umberto I

Results and Publications

Publication and dissemination plan
Planned publication in the journal BMC Pediatrics

Intention to publish date
01/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/07/2017		Yes	No