

Effects of inhaled hypertonic saline in children with cystic fibrosis

Submission date 04/05/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/07/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/10/2017	Condition category Genetic Diseases	☐ 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 Raffaella Nenna

Contact information

Type(s)
Scientific

Contact name
Dr Raffaella Nenna

Contact details
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Additional identifiers

Protocol serial number
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)

Primary study design

Interventional

Study design

Double-blind randomised cross over trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 Years

Upper age limit

6 Years

Sex

All

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

Rome

Italy

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Sponsor information

Organisation

Sapienza University of Rome

ROR

<https://ror.org/02be6w209>

Funder(s)**Funder type**

University/education

Funder Name

Policlinico Umberto I

Results and Publications**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