ISRCTN10829073 https://doi.org/10.1186/ISRCTN10829073

African children's oxygen administration and nutrition clinical trial

Submission date
18/05/2018

Recruitment status
No longer recruiting

Registration date
06/06/2018

Overall study status
Completed

Last Edited
25/06/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Worldwide, pneumonia remains the leading cause of death in children. The major risk factor for this is poor nutritional status. Children with severe malnutrition will have nutritional support, but children who are less severely malnourished at the moment do not receive any additional nutritional support. A trial called COAST is currently examining treatment recommendations regarding which children should receive oxygen. Children enrolled in the COAST trial who survive 48 hours will then be enrolled into this study, which is examining whether supplementing the usual diet with a Ready-to-Use therapeutic feed (usually given to children with severe malnutrition) for the next 56 days improves their outcomes (measured by better growth in terms of the fatness of their arms, called mid-upper arm circumference, and whether they survive 6 months after their initial hospital admission).

Who can participate?
Children taking part in the COAST trial (ISRCTN15622505) who survive to 48 hours and are older than 6 months

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives supplementary feeding for 56 days (8 weeks) using one 92 g sachet (500 Kcal) per day of Ready to Use Therapeutic Feeds (RUTF) in addition to their usual diet. RUTF is taken once daily direct from the packet, with no need for dilution or cooking, and is given in addition to usual diet. The other group receives usual diet alone (standard of care). Mid-upper arm circumference is measured at the start of the study and after 90 days.

What are the possible benefits and risks of participating?
Benefits are frequent clinical visits for health checks and assessment of nutritional status, and referral or treatment for complications. Risks are minimal as RUTF is widely used and has minimal complications. Allergy to nuts and intolerance to milk will be checked by a test dose in hospital.

Where is the study run from?
1. Mulago National Referral Hospital (Uganda)

2. Mbale Regional Referral Hospital (Uganda)
3. Soroti Regional Referral Hospital (Uganda)
4. Kilifi County Hospital (Kenya)
5. Coast Provincial General Hospital (Kenya)

When is the study starting and how long is it expected to run for?
June 2018 to October 2022

Who is funding the study?
1. European and Developing Countries Clinical Trials Partnership
2. Joint Global Health Trials (MRC, Wellcome Trust, Dfid)

Who is the main contact?
1. Prof. Kathryn Maitland
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2. Mr Emmanuel Oguda
EOguda@kemri-wellcome.org

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v 1.0, PACTR202106635355751

Study information

Scientific Title
Children’s oxygen administration and nutrition strategies trial

Acronym
COAST-Nutrition

Study objectives
The trialists propose that additional nutritional support using ready to use supplementary feeds in children recovering from severe pneumonia will provide additional energy-rich, protein, fat and micronutrients to help meet the additional nutritional requirements and to decrease the risk of catabolism.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Imperial College Research Ethics Committee, 23/09/2017, Protocol Number 15IC3100

Study design
Multicentre open-label randomisation controlled trial of nutritional support. All allocations masked.

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 use the contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Severe pneumonia

Interventions
The randomisation lists are prepared and kept at the ICNARC CTU, London. Opaque and sealed randomisation envelopes are used to allocate the study interventions.

1. Supplementary feeding for 56 days (8 weeks) using one 92 g sachet (500 Kcal) per day of Ready to Use Therapeutic Feeds (RUTF) in addition to their usual diet (intervention). RUTF is taken once daily direct from the packet, thus no need for dilution or cooking and given in addition to usual diet
2. Usual diet alone (control, standard of care)

Intervention Type
Other

Primary outcome measure
Mid-upper arm circumference (MUAC) measured by MUAC tape (supplied by UNICEF) at baseline and 90 days and/or as a composite with 90-day mortality

Secondary outcome measures
Re-admission to hospital will be defined as hospitalisation

Overall study start date
01/06/2018

Completion date
28/10/2022

Eligibility

Key inclusion criteria
Children enrolled in the COAST trial (ISRCTN15622505) who survive to 48 hours and are older than 6 months

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Sex
Both

Target number of participants
840

Total final enrolment
846

Key exclusion criteria
Children with severe malnutrition (defined as mid upper arm circumference <11.5cm)

Date of first enrolment
01/06/2018

Date of final enrolment
20/04/2022

Locations

Countries of recruitment
Kenya

Uganda

Study participating centre
Jinja Regional Referral Hospital
Rotary Rd
Jinja
Uganda
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Study participating centre
Mbale Regional Referral Hospital
Department of Paediatrics
Pallisa Road Zone
Mbale
Uganda
PO Box 921

Study participating centre
Soroti Regional Referral Hospital
Soroti
Uganda
PO Box 289

Study participating centre
Kilifi County Hospital
KEMRI Wellcome Trust Research Programme
Kilifi
Kenya
PO Box 230

Study participating centre
Coast Provincial General Hospital
Bondeni, Kisauni Rd
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PO Box 90231

Sponsor information

Organisation
Imperial College, London

Sponsor details
Joint Research Compliance Office
Room 221
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Norfolk Place
London
England
United Kingdom
W2 1PG
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Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type

Research organisation

Funder Name
European and Developing Countries Clinical Trials Partnership

Alternative Name(s)
Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaios Clínicos, The European & Developing Countries Clinical Trials Partnership, European and Developing Countries Clinical Trials, EDCTP

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Netherlands

Funder Name
Joint Global Health Trials (MRC, Wellcome Trust, Dfid)

Results and Publications

Publication and dissemination plan
The trialists aim to publish COAST Nutrition protocol and the statistical analysis plan will be available on request. Once the results are ready they will submit for publication in a peer reviewed journal with open access to the paper. They aim to contact key stakeholders (ministries of health, policy makers and specialists in nutritional research) with their results.

All publications and presentations relating to the trial will be authorised by the Trial Management Group (TMG). The first publication of the trial results will be in the name of the TMG, if this does not conflict with the journal's policy. If there are named authors, these will include the chief investigator, Trial Statistician and Trial Manager. Members of the TMG, Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) and other contributors will be cited by name, if this does not conflict with the journal's policy.

Authorship of sub studies initiated outside of the TMG will be according to the individuals involved in the project but must acknowledge the contribution of the TMG. The TSC is the custodian of the data and specimens generated from the trial; trial data are not the property of individual participating investigators or health care facilities where the data were generated. During the course and following completion of the trial there will be publications, including manuscripts and abstracts for presentations at national and international meetings, as well as the preparation of manuscripts for peer-reviewed publication. In order to avoid disputes

regarding authorship, a consensus approach will be established that will provide a framework for all publications derived in full or in part from this trial. Authorship criteria will be determined using the guidelines provided by The International Committee of Medical Journal Editors.

The trialists plan to communicate throughout the course of the trial with the following audience groups: national policymakers (Ministry of Health, child health services); international policymakers (WHO, UNICEF); healthcare workers, nursing and paediatric associations, and NGOs involved in providing treatment or advocacy for children with severe respiratory diseases and nutritional support; academics working in related fields; communities where the trial is taking place; and organisations who provide training to healthcare workers.

Engaging with key audiences will be helped by the links the trial team already have with some key stakeholders. The trial results will be made available in a number of different formats and fora, in order to be appropriate for and accessible to different audiences. There will be face-to-face meetings; workshops; open access peer-reviewed publication; policy briefs; presentation at international conferences; press releases; lay summaries; and websites. Depending on the results films and radio programmes may also be developed and distributed; and the trialists will consult with members of the intended audiences to assess what other opportunities and tools for communicating should be used.

Intention to publish date
30/05/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from (Kathryn Maitland k.maitland@imperial.ac.uk) on reasonable request 6 months after publication of the clinical trial. The ownership of the COAST Nutrition dataset will lie with the Trial Steering Committee (TSC), who will approve all requests for use of trial data before and after the trial ends. The dataset will be held electronically for at least 20 years after the end of the trial in accordance with local policies. The Data Sharing Policy states that proposals to use COAST Nutrition data and samples will be welcomed, and supported widely where this does not conflict with existing research plans within the trial team. Independent oversight of the data access process will be provided by TSC independent members and Imperial College, London (the trial sponsors). In consenting the the study the guardians/parents understood that this may include data sharing with other researchers. All data will be partially de-identified.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/09/2021	05/11/2021	Yes	No
Statistical Analysis Plan	version 1	11/07/2022	13/05/2024	No	No
Results article		14/05/2024	20/05/2024	Yes	No
Other publications	Nested prospective cohort study results of body composition proxy measures	30/09/2024	02/10/2024	Yes	No

Other publications	secondary analysis	06/06/2025	25/06/2025	Yes	No