Can rehabilitation delivered immediately on hospitalisation for an acute exacerbation of chronic respiratory disease improve long term health outcomes?

| Submission date 07/08/2009 | Recruitment status No longer recruiting | [X] Prospectively registered [_] Protocol |
|-------------------------------------|---|--|
| Registration date 02/10/2009 | Overall study status Completed | Statistical analysis plan [X] Results |
| Last Edited 10/07/2014 | Condition category Respiratory | [] Individual participant data |

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 N/A

Study information

Scientific Title

Can rehabilitation delivered immediately on hospitalisation for an acute exacerbation of chronic respiratory disease improve long term health outcomes? A randomised controlled trial

Acronym

The REACH trial

Study objectives

The hypothesis is that an early and proactive rehabilitation strategy which is delivered immediately on hospitalisation for an acute exacerbation of chronic respiratory disease will prevent the decline in physical function associated with the exacerbation, improve clinical outcomes and reduce the risk of subsequent hospitalisation.

Ethics approval required

Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Prospective parallel group randomised single blind controlled clinical trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied Chronic respiratory disease

Interventions

Treatment for patients in the intervention group will start within 48 hours of admission for an acute exacerbation of chronic respiratory disease. It will take the form of a daily, individually prescribed, graduated exercise and strength training programme and will continue until

discharge. After discharge, patients will continue a home-based customised rehabilitation programme for six weeks. Patients in the control group will receive 'best usual care' from the medical, nursing, physiotherapy and occupational therapy teams.

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

Hospital readmission rate at 12 months

Secondary outcome measures

1. Exercise capacity, measured at discharge home, 6 weeks after randomisation, 6 months after discharge and 12 months after discharge

2. Health status, measured at discharge home, 6 weeks after randomisation, 6 months after discharge and 12 months after discharge

3. Psychological wellbeing, measured at discharge home, 6 weeks after randomisation, 6 months after discharge and 12 months after discharge

4. Muscle strength and thickness, measured at discharge home, 6 weeks after randomisation, 6 months after discharge and 12 months after discharge

5. Biomarkers, measured at discharge home, 6 weeks after randomisation, 6 months after discharge and 12 months after discharge

6. Spirometry, measured at discharge home, 6 weeks after randomisation, 6 months after discharge and 12 months after discharge

7. Length of stay, measured at discharge home

8. Nutritional status, measured at 6 weeks after randomisation, 6 months after discharge and 12 months after discharge

9. Muscle structure changes, measured at 6 weeks after randomisation, 6 months after discharge and 12 months after discharge

10. Focus groups for psychological analysis, measured at 12 months after discharge

11. Healthcare utilisation, measured at 12 months after discharge

Overall study start date

01/01/2010

Completion date

30/09/2013

Eligibility

Key inclusion criteria

 Patients aged 40 and over of either sex who are admitted to hospital with an acute exacerbation of chronic respiratory disease
 Ability to give informed consent

Participant type(s)

Patient

Age group

Adult

Sex Both

Target number of participants 484

Key exclusion criteria

1. Musculoskeletal or neuromuscular conditions that significantly contribute to exercise limitation

2. Psychiatric or neurological conditions that render the patient unable to comply with the rehabilitation programme

3. Not living independently at the time of admission

4. Admission for an acute myocardial infarction

5. Terminal disease with an estimated survival time of less than three months

6. Four or more hospitalisations for acute exacerbations of chronic respiratory disease in the preceding 12 month period

Date of first enrolment 01/01/2010

Date of final enrolment 30/09/2013

Locations

Countries of recruitment England

United Kingdom

Study participating centre Department of Pulmonary Rehabilitation Leicester United Kingdom LE3 9QP

Sponsor information

Organisation University Hospitals of Leicester NHS Trust (UK)

Sponsor details

Headquarters Gwendolen House Gwendolen Road Leicester England United Kingdom LE5 4QF +44 (0)116 287 1471 carolyn.maloney@uhl-tr.nhs.uk

Sponsor type Hospital/treatment centre

Website http://www.uhl-tr.nhs.uk/

ROR https://ror.org/02fha3693

Funder(s)

Funder type Government

Funder Name

National Institute of Health Research (NIHR) (UK) - Collaboration for Leadership in Applied Health Research and Care - Leicestershire, Northamptonshire and Rutland (CLAHRC LNR)

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------|---------|--------------|------------|----------------|-----------------|
| <u>Results article</u> | results | 08/07/2014 | | Yes | No |