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Will an individualised service improve medicine administration to adults with dysphagia - a pilot study?

Submission date 29/04/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/04/2010	**Overall study status** Completed	
Last Edited 14/07/2016	**Condition category** Other	

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
7288

Study information

Scientific Title
A non-randomised process of care case-controlled study of an individualised service to improve medicine administration to adults with dysphagia

Acronym
DYS-MED

Study objectives
To estimate:
1. The likely effect of a dedicated pharmacist's introduction of individualised medicine administration guides (I-MAGs) on nurses' clinical practice and medicine administration error (MAE) rate (primary outcome measure)
2. The likely effect of the introduction of I-MAGs on patients' health-related quality-of-life, post-discharge adherence and hospitalisation (secondary outcome measures)
3. Whether randomisation for such a trial should occur at ward or hospital level
4. The most efficient method of patient recruitment, the likely 'drop out' rate, the best outcome measures, and the feasibility of a full cost-effectiveness analysis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Essex 2 Research Ethics Committee (REC) approved on the 16th January 2009 (ref: 08/H0302 /153)

Study design
Non-randomised interventional and observational process of care case-controlled study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Age and ageing

Interventions
Whilst an inpatient the intervention patient group will receive their medicines as prescribed by the doctors caring for them in the normal way. A pharmacist, employed for the purposes of the study, will develop an individualised medicine administration guide for each patient which will be used by the nurses administering medicines to those patients to guide appropriate preparation and administration. Prior to discharge the pharmacist employed for the project will adapt the individualised medicine administration guide to reflect the medcines the patient is to be discharged on, and will teach the patient how to use it. Copies will also be sent to the patient's GP and local community pharmacist.

The control group will not have these individualised medicine administration guides.

Both groups will be followed up for six months after discharge from hospital and will be asked to complete four questionnaires on discharge, six weeks and six months post discharge.

The primary outcome measure for the study is a decrease in medicine administration errors by the nurses administering medicines to patients in the intervention and control groups. The nurses will be given a questionnaire about aspect of medicine administration at the begining of the study and 16 will be observed administering medicines to patients on the four wards involed, i.e. the two intervention and two contiol wards. After six months the questionnaire will be re-administered and 16 medicine adminisration rounds will be observed.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Whether the introduction of individualised medicine administration guides reduce the number of medication errors.

Secondary outcome measures
The likely effect of the introduction of individualised medicine administration guides on health related quality of life measures, patient satisfaction with information and pharmaceutical care and medicine adherence. These will be measured at patient discharge, six weeks and six months after discharge.

Overall study start date
01/07/2010

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. Patients with dysphagia
2. Based in three Care of the Elderly wards and one Stroke unit at the Norfolk and Norwich University Hospital

3. Consent to take part
4. Taking medication
5. Registered nurses working on the same four wards who consent to take part

Participant type(s)
Patient

Age group
Senior

Sex
Not Specified

Target number of participants
Planned Sample Size: 360; UK Sample Size: 360

Key exclusion criteria
Unable to communicate in English

Date of first enrolment
01/07/2010

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Pharmacy
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
University of East Anglia (UK)

Sponsor details

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Sponsor type
University/education

Website
http://www.uea.ac.uk/

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

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?
Results article	results	01/11/2012		Yes	No