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The use of a patient ward transfer as a trigger for the application of clinical pharmacy

Submission date	Recruitment status	[ ] Prospectively registered
22/03/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/08/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/08/2011	Other	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Dirk Ramaekers

Contact details
Leopoldstraat 26
Antwerp
Belgium
2000
dirk.ramaekers@zna.be

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
072010FOD

Study information

Scientific Title

The transfer-trigger as a basic for the application of clinical pharmacy

Study objectives
1. A total inventory and analysis of the communication channels and different types of documents involved in a patient transfer
2. A proposal for improvement and optimization of these documents
3. A comparison of drug therapy before and after each transfer
4. An analysis of the differences of these comparisons
5. A proposal for interventions/recommendations to medication management by the clinical pharmacist following the transfers
6. Acceptance measurement of the interventions / recommendations
7. Discharge management

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board ZNA/OCMW Antwerpen OG 031-009 ref: 3754

Study design
Prospective randomized two-arm multicenter study

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
The clinical pharmacist receives a signal when an enrolled patient is transferred. This signal is the cue for a total drug analysis of the medication therapy before and after transfer. This happens no later than 2 days after transfer. The patients home medication is studied retrospectively.

Interventions
Implementation Phase:
For each enrolled patient the drug therapy before and after each transfer will be compared and any differences will be recorded on a standard document. The following differences will be reported:
1. Differences in dosage
2. Differences in method of administration
3. Dosage adjustments depending on organ function

4. Additions or eliminations of a drug
5. Incorrect medication

As it is possible that a patient can transfer several times, after each transfer a new document will be completed. The enrolled patients are followed throughout their stay in the ZNA. 1. The patients are randomised using the last digit of their admissions number:
1.1. Odd number = observation group
1.2. Even number = intervention group
2. Recommendations for intervention (where necessary) are recorded for all patients.
3. The interventions/recommendations are only implemented/proposed in the intervention group.
4. The included patients will be randomized and divided into 2 groups:
4.1. In the control group there will be only observation but no interventions by the clinical pharmacist. Subsequent changes to the medication by other care providers with a positive impact on the drug therapy are also noted.
4.2. The drug therapy of the intervention group will be viewed by the clinical pharmacist who will make interventions or recommendations where appropriate.
4.3. The clinical pharmacist will also examine whether the therapy is consistent with the current medication policy endorsed by the MFC (formulary medication).
5. Interventions can include:
5.1. Stopping or reducing treatment
5.2. Starting or resumption of treatment
5.3. Substitution/replacement
5.4. Change of route of administration/formulation
5.5. Dose adjustment
5.6. Frequency adjustment
5.7. Change of route of administration
5.8. Improvement of monitoring/follow up
5.9. Explanation of the discharge procedure
6. The interventions will be documented using a standard intervention form consisting of the following:
6.1. Reason to intervene
6.2. Intervention
6.3. Outcome
6.4 Medical/economic impact
7. The four parts are completed for both the intervention group and the control group.
8. In the control group the intervention will not be implemented.
9. Both intervention and outcome will be assessed according to their relevance and will be compared
10. When a patient is discharged, the clinical pharmacist will do a proposal for the discharge medication. This proposal takes into account the possible substitutions that would have happened in the hospital and ensures that they are switched back to the original drug.
11. There needs to be clear procedures in place to inform the prescriber which medication substitutions need to be prescribed on discharge
12. Communication between doctor - nurse - pharmacist - patient is crucial. We will investigate how this can be done most efficiently.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
1. These are only applicable for the intervention group
2. Determined the day after the intervention
3. Importance of the interventions are evaluated
4. The difference in outcome between the two groups will serve as a measure of the importance of a clinical pharmacist on the ward
The possible primary outcome/acceptance among the intervention group is (a) implementation of the intervention or (b) no implementation. Also in the control group, the primary outcome can (a) be positive by implementing interventions or recommendations by other health care providers on their own initiative or (b) negative if no third party has intervened.

Secondary outcome measures
The degree of relevancy will be determined by an expert group:
1. Medical impact
2. Economic impact

Overall study start date
06/12/2010

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Hospitalised patients above 15 years of age
2. Patients should have stayed a minimum of three days in intensive care and then undergo a transfer to a ward with surgical, medical or geriatric beds

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
600

Key exclusion criteria
Patients with a Do Not Resuscitate (DNR) code of 2 and 3 are excluded (patients where it has been agreed that certain treatments should not be started or should be withdrawn)

Date of first enrolment
06/12/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Belgium

Study participating centre
Leopoldstraat 26
Antwerp
Belgium
2000

Sponsor information

Organisation
ZNA Hospital Network Antwerp (Belgium)

Sponsor details
c/o Ms Sarah De Broe
Lange Beeldekensstraat 267
Antwerp
Belgium
2060
sarah.debroe@zna.be

Sponsor type
Hospital/treatment centre

Website
http://www.zna.be/

Funder(s)

Funder type
Government

Funder Name
Belgian Goverment

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