Admission of elderly medical patients to fast track or standard hospitalisation: protocol for a randomised trial

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ABSTRACT

INTRODUCTION : Emergency department-based short stay units (SSUs) are increasingly being introduced to provide accelerated care. The effects of treatment in SSUs for elderly medical patients are not well-studied.

METHODS: The ELDER trial is a single-blinded, randomised parallel trial with 1:1 allocation between hospitalisation in an SSU (intervention) and the Department of Internal Medicine (standard care). The study is conducted at Holbaek Hospital, Denmark. Elderly patients are screened for inclusion if an emergency physician assesses that treatment in an SSU is possible. Eligible participants are patients aged ≥ 75 years needing in-hospital treatment of an acute medical problem and who are stable upon admission. The primary outcome is 90-day all-cause mortality. Secondary outcomes include: length of stay in hospital, incidence of complications during hospitalisation, rate of unplanned readmissions and change in instrumental activities of daily living. We aim at recruiting 430 patients based on an estimated effects size of reducing mortality by 10%. All outcome measures will be assessed in an intention-to-treat analysis. Recruitment started on 5 January 2015. By 16 October 2015, we have enrolled 203 patients. An interim safety analysis is scheduled.

CONCLUSION: In the ELDER trial, we explore benefits and harms related to treatment in an SSU for elderly medical patients compared with standard hospitalisation.

FUNDING: Region Zealand's Forskningsfond, the Tryg Foundation and University of Copenhagen.

TRIAL REGISTRATION: clinicaltrials.gov identifier: NCT02395718.

Emergency department (ED)-based short stay units (SSUs) have been established to provide accelerated care and brief hospitalisation for selected patients. SSUs are believed to optimise patient care through a shorter time to diagnosis which minimises the time until patients return to baseline health status and decreases healthcare expenditures without compromising quality of care [1, 2]. Hospitalisation in SSUs may be feasible for the elderly; however, this is not well studied. The provision of care for elderly patients is complicated for many reasons, e.g. because age-related biological changes lead to frailty that is often accompanied by multiple chronic diseases. Elderly also display symptoms of acute illness differently which can cause delays in diagnosis or even misdiagnosis [3]. Moreover, elderly are at higher risk of experiencing critical functional decline and complications during hospitalisation.

At Holbaek Hospital, Denmark, the SSU is called the Quick Diagnostic Unit (QDU). Patients are admitted to the QDU via the ED for observation, further diagnostics and/or treatment. They must be stable and ambulatory under normal circumstances. Primarily, patients are admitted for treatment of minor medical ailments (e.g. anaemia, urinary tract infection) [4]; however, the QDU also manages some patients with deterioration of chronic diseases or patients with diffuse symptoms that cannot be handled in an outpatient setting. The QDU only admits patients where brief hospitalisation seems likely (< 72 hours). Finally, the QDU serves as a buffer for ED overcrowding [5]. In an audit comparing treatment of elderly patients in the QDU (n = 42) with treatment in the Department of Internal Medicine (DIM, n = 103), we found a lower mortality (7% versus 22%, p = 0.05), a shorter length of stay (2.8 ± 2.0 days versus 7.7 ± 7.5, p < 0.001), less adverse events (5% versus 19%, p = 0.04) and a lower readmission rate (2% versus 23%, p = 0.001) in the QDU group. These findings are promising, but merely observational. Thus, we wanted to study putative differences between fast track and traditional treatment settings more rigorously in the present trial. The aim of this trial is to explore both the benefits and the drawbacks of treating elderly medical patients (≥ 75 years) in the QDU compared with standard treatment at the DIM.

METHODS

The ELDER trial (clinicaltrials.gov identifier: NCT02395718) is an on-going, single-centre, randomised trial, using parallel groups with 1:1 allocation between treatment in the QDU (intervention group) and the DIM (control group) at Holbaek Hospital, Denmark. The trial is designed in compliance with the Consort Statement. The

PROTOCOL ARTICLE

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Dan Med J 2016;63(3):A5189

trial was approved by the Regional Ethical Committee and the Danish Data Protection Agency.

Participants

Patients are screened for inclusion in the study if the treating physician has decided that the patient is a candidate for treatment in the QDU: patient has an expected stay within a few days and is not physically dependent on extensive nursing care. Patients are eligible for inclusion if they are: 1) 75 years or older; 2) admitted through the ED for treatment of a medical problem; 3) green-tag triaged in the ED (the Danish Emergency Process Triage Model sorts patients into five levels according to the urgency of their medical condition. Each category is labelled by a unique colour, thus 1 = red = resuscitation; 2 = orange = emergent; 3 = yellow = urgent; 4 = green = less urgent; and 5 = blue = not urgent [6]).

Patients are excluded if they: 1) have previously participated in the trial; 2) are participating in other clinical trials; 3) have no Danish civil registration number; 4) reside abroad; 5) require help to go to the toilet in daily life; 6) are unaware of date, time and location, or own data (name, birth date); or if: 7) there are no beds available in the QDU; and 8) informed consent cannot be obtained.

Recruitment and randomisation

Patients are recruited in the ED after initial work-up and treatment. Hereafter, the physician screens the patients for trial eligibility. If a patient fulfils all inclusion criteria and no exclusion criteria, written consent is obtained. Patients are randomised using "OPEN Randomize" which is a web-based randomisation tool provided by the Odense Patient Data Explorative Network (OPEN), Odense University Hospital, Odense, Denmark. A computer-generated randomisation sequence with variable block size is used, and allocation concealment is ensured through a computer-generated list.

There is a growing interest for fast-track care. We assess potential benefits and harms related to treatment of elderly medical patients in an emergency department-based short stay unit.

Description of intervention and control

Treatment in the Quick Diagnostic Unit (intervention)

The QDU is integrated into the ED. The unit accommodates up to 16 patients. During day-time (8 a.m. to 4 p.m.), it is staffed by one chief physician (specialist in internal medicine), one additional rotating senior or chief physician, one intern, three nurses and a secretary. In the evening (4 p.m. to 11 p.m.), the QDU is manned by two nurses, and during night-time (11 p.m. to 7 a.m.) by one nurse. In case of an emergency, the nurses from the ED can assist at any time. The physicians on call in the ED care for the QDU in the evening and night-time (in the evening: two or three senior physicians and two or three interns; and at night: one senior physician and two or three interns). Hence, both nurses and physicians rotate on a daily basis between the ED and the QDU. In the QDU, discharge planning is initiated as soon as the patient is admitted. Diagnostic tests and treatments can be carried out on the same terms as in the ED. The ED, including the QDU, has its own point of care laboratory which is staffed from 8 a.m. to 10 p.m., as well as an X-ray facility which is staffed from 10 a.m. to 6 p.m. Point-of-care ultrasonography can be performed around the clock. More advanced diagnostic procedures such as computed tomography (CT) or magnetic resonance imaging (MRI) are performed at the Department of Radiology on a fast-track basis. If necessary, additional specialist evaluations from various in-house specialists can be facilitated. Simultaneously with the medical treatment; physical therapists and occupational therapists train and optimise the patients' level of functioning.

Treatment in the Department of Internal Medicine (control)

Patients in the control group are treated as conventionally at one of the seven wards of the DIM. The DIM has 140 beds, and each ward accommodates approximately 20 patients on average. During week-days from 8 a.m. to 3.30 p.m., each ward is manned by two or three senior physicians (predominantly specialists in internal medicine), one or two interns and six or seven nurses/nurse assistants. From 3 p.m. to 11 p.m., each ward is manned by three or four nurses/nurse assistants and during the night from 11 p.m. to 7 a.m. by two or three nurses/nurse assistants. From 3.30 p.m. to 8 a.m. at weekdays and during the whole day at weekends, the seven wards are staffed by one senior physician and two interns; both are on call in-house. An additional senior physician is on call until 9 p.m.

The interns usually see all newly admitted patients for evaluation of acute issues. Afterwards, an internal medicine specialist sees the patients: stable patients admitted during the daytime from 8 a.m. to 4 p.m. are usually seen by the senior physician on call at night, whereas stable patients admitted after 3.30 p.m. are

TABLE 1

Department staffing and availability of diagnostic equipment.

	Day		Evening		Night	
	QDU	DIM	QDU	DIM	QDU	DIM
Patient capacity, n	16	20	16	20	16	20
Staff						
Nurse or nurse assistant (patients per staff member)[a]	(~5)	(~3)	(~8)	(~5-7)	(~16)	(~7-10)
Senior physician (patients per staff member)[a]	(~5)	(~4-7)				
Physicians in training (patients per staff member)[a]	(~5)	(~4-7)				
Physiotherapist (patients per staff member)[a]	(~16)	(~20)	–	–	–	–
Occupational therapist (patients per staff member)[a]	(~16)	(~20)	–	–	–	–
Diagnostics						
Point-of-care laboratory	✓	–	✓	–	–	–
Central laboratory	✓	✓	✓	✓	✓	✓
Point-of-care laboratory, care X-ray and ultrasound	✓	Only echocardiography	✓ (X-ray until 6 p.m.)	–	✓[b]	–
Services at Department of Radiology (e.g. X-ray, MRI, CT)	✓	✓	✓	✓	✓	✓

CT = computerised tomography; DIM = Department of Internal medicine; MRI = magnetic resonance imaging; QDU = Quick Diagnostic Unit.
= staff member working in the ward; = staff member on call in house; / = occasional additional staff.
a) Physician specialists and interns are pooled into 1 group when calculating number of patients per physician.
b) If specialist on call is able to perform ultrasound.

usually seen by a senior physician during daytime the next day. The senior physician is responsible for working out a plan for further diagnostics and treatment. Treatment by physiotherapists and occupational therapists or other medical specialists is available upon request. Contrary to the QDU, the DIM wards offer no point-of-care laboratory or fast-track diagnostics. Thus, analyses of blood samples are performed at the central laboratory and radiological procedures at the Department of Radiology. Illustration of differences in department staffing and availability of diagnostic equipment between the QDU and the DIM are presented in **Table 1**.

Safety

If a patient's condition deteriorates at any time, intensified monitoring and care including, if needed, intensive care interventions will be carried out without any restrictions, regardless of treatment allocation.

Data

Data are collected on printed case report forms with unique barcodes. Blinding of participants or services to the allocation is not possible. Data will be entered independently by two researchers in an electronic database; any inconsistencies will be resolved. Data will be anaVnvolved in the project. After statistical analyses are completed, all data and results will be presented to the Steering Committee under blinded codes for allocation group. Labels for group allocation will first be revealed after all analyses have been completed.

Outcomes and measurements

The primary outcome is 90-day all-cause mortality. The secondary outcomes are: 1) all-cause mortality within the full observation period; 2) unplanned readmission rate within 30 days from date of discharge; 3) in-hospital mortality; 4) transfer to other ward during hospitalisation; 5) length-of-stay in hospital; 6) change in Lawton's Instrumental Activities of Daily Living (iADL) score within 90 days from admission; 7) change of living facility within 90 days from admission; and 8) occurrence of complications per day of hospitalisation. The following will be classified as a complication: a) nosocomial infection; b) medication error; c) deep venous thrombosis; d) pulmonary embolism; f) delirium; g) decubitus ulcers; h) post-procedural haemorrhage; i) in-hospital fractures or falls; j) gastrointestinal haemorrhage; and k) cerebral infarction.

After inclusion, we register the following demographic characteristics: age, sex, marital status, residen-

tial status, level of education, home-care recorded as never/daily/less than daily, smoking habit and alcohol consumption. For health status, we register the following: reason for admission, Charlson Comorbidity Index, list of medications, and iADL score.

On day 90 after admission, we evaluate the secondary outcome measures for each participant by phone call and chart review. Complications will be evaluated through a chart review by two independent researchers; disagreements will be resolved by consultation with a third researcher.

We will retrieve mortality data from the Danish civil registration system. At day 90 after the last patient has been enrolled, an independent data manager will make the retrieval of all mortality data.

Data monitoring and interim analyses

An independent data monitoring committee (DMC) will be established to evaluate safety and efficacy at an interim analysis of 90-day mortality. The mortality data will be presented to the DMC under a code blinding for allocation group when the 90-day mortality data of 215 trial participants have been obtained, and/or 30 deaths have been documented during the trial. If the interim analysis of 90-day mortality data is significant with a p-value < 0.05 for benefit or harm of the intervention, the DMC can advise the Steering Committee to stop the trial.

Statistical analysis

Demographic and baseline data will be summarised by descriptive statistics. The outcome measures will be analysed for all randomised patients in an intention-to-treat analysis; differences in groups will be analysed by chi-squared or Student's t-test, where appropriate. Cox-regression and univariate and multivariate logistic analysis will be used. Relative risks will be reported with 95% confidence intervals. Survival will be illustrated with Kaplan-Meier estimates. p-values lower than 0.05 will be considered statistically significant.

Sample size

Sample size is determined by the primary outcome: 90-day mortality. Prior to the trial, we retrospectively assessed 90-day mortality in elderly medical patients (75 years or older) with green tag triage upon arrival who had all been admitted to inward hospitalisation at Holbaek Hospital. The 90-day all-cause mortality was 5% in patients treated in the QDU and 17% in patients treated at the DIM. In another retrospective study, 180-day all cause mortality was 7% in the QDU group and 22% in the DIM group. We aim to confirm or reject an intervention effect of reducing mortality from 15% to 5%. The sample size with a type 1 error risk of 5% and a type 2 error risk of 10% (90% power) is estimated to require 400 patients, 200 in each group. Because we anticipate some dropouts, we aim to include 430 participants in the study.

Trial registration: clinicaltrials.gov identifier: NCT02395718.

DISCUSSION

The ELDER trial addresses important aspects of treating the fast growing and challenging elderly patient population. If hospitalisation in an SSUs is beneficial for the elderly, it may contribute to improved health outcomes, e.g. short hospitalisation could potentially reduce loss of functional capacity, risk of complications or other adverse events related to hospitalisation, and it could lower mortality. On the other hand, it may be problematic: the elderly may feel insecure about being discharged early; or their condition may not be thoroughly treated before they return home, which could lead to more readmissions or adverse events at home.

This trial has several strengths: the randomised design minimises risk of bias and confounding, data analysis will be performed in a blinded manner and labels for allocation will only be revealed after analyses have been completed. Although other options would have been possible [7], our primary outcome, mortality, is a hard endpoint, which ensures scientific rigour. As mortality data will be retrieved from the Danish Civil Registration System, we will be able to obtain complete data of the primary outcome. The trial also has limitations: we do not include very frail elderly patients, it is impossible to blind involved healthcare personnel and participants; and because this trial is the first of its kind, the sample size calculation is based on estimates from retrospective studies, which entails a risk of type 2 error and we may have overestimated the intervention effect.

CONCLUSION

The ELDER trial is a pragmatic randomised trial that evaluates the effect of treatment in an SSU, the QDU, for elderly medical patients. It aims to contribute to answer the question: Is hospitalisation in an SSU feasible, beneficial or harmful for elderly medical patients?

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ACCEPTED: 16 November 2015

CONFLICTS OF INTEREST: Disclosure forms provided by the authors are available with the full text of this article at www.danmedj.dk

LITERATURE

1. Daly S, Campbell D A, Cameron P A. Short-stay units and observation medicine: a systematic review. Med J Aust 2003;178:559-63.
2. Konnyu KJ, Kwok E, Skidmore B et al. The effectiveness and safety of emergency department short stay units: a rapid review. Open Med 2012;6:e10-e16.
3. Resnick NM, Marcantonio ER. How should clinical care of the aged differ? Lancet 1997;350:1157-8.
4. Stenqvist C, Rasmussen SW, Schmidt TA. Treatment of transfusion requiring anemia in a quick diagnostic unit integrated in an emergency department setting. Scand J Trauma Resusc Emerg Med 2013;21:A48.

5. Petersen DB, Schmidt TA. Quick diagnostic unit integrated in an emergency department setting reduces medical admissions – an observational study. J Hosp Adm 2013:17.
6. http://deptriage.dk/ (17 Oct 2015).
7. Madsen M, Kiuru S, Castrèn M et al. The level of evidence for emergency department performance indicators: systematic review. Eur J Emerg Med 2015:22;298-305.