Supported Fast track multi-Trauma Rehabilitation Service (SFTRS)

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23753

Source
NTR

Brief title
SFTRS

Health condition

Multi-trauma patients admitted to one of the accident & emergency departments (A&E) of the participating hospitals are included in this study. Multi-trauma is defined as having at least 2 or more injuries of whichat least 1 is life threatening, including a) trauma with an Injury Severity Scale score ISS >= 16, b) complex multiple injuries on both lower extremities, c) a combination of one upper and one lower extremity injury, the latter of which can not be used in load-bearing, or d) complex pelvis/acetabulum fractures.

Sponsors and support

Primary sponsor: Rehabilitation Foundation Limburg (SRL), Departments of Traumatology and Research
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

- Generic quality of life: SF-36

- Functional health status: Functional Independence Measure (FIM)

Secondary outcome

- Extent to which individual ADL treatment goals are met: Canadian Occupational Performance Measure (COPM)

- Anxiety and depression: Hospital Anxiety and Depression Scale (HADS)

- Cognitive functioning: Mini-Mental State Examination (MMSE)

Also costs will be assessed using the PRODISQ, a cost questionnaire and hospital database data.

Study description

Background summary

OBJECTIVE:

The main objective is to examine the effectiveness, the costs and the cost-effectiveness of an integrated fast track rehabilitation service for multi-trauma patients (SFTRS) involving dedicated early rehab intervention programs. The SFTRS is contrasted with conventional multi-trauma care. In the SFTRS the rehabilitation physician is routinely involved in a very early stage post-trauma, facilitating early start of multidisciplinary rehab treatment involving:

a) early non-weight bearing physical therapy, psychological and social counselling

b) early transfer to a centralised, specialised trauma rehab unit equipped with facilities for early training programs

c) early individual rehab goal setting
d) close co-operation and exchange of views and experiences between the trauma surgeon, the rehabilitation physician and the rehab team.

SFTRS also features shorter lengths of stay and well documented treatment protocols.

RESEARCH QUESTION:

Which of 2 services, i.e. Conventional multi-Trauma Care Service or Supported Fast track multi-Trauma Rehabilitation Service(SFTRS), is most (cost-)effective?

STUDY DESIGN:

In a multi-centre, non-randomised clinical trial 164 (2x82) mult-trauma patients will participate. The duration of follow-up is 12 months. One group of patients will follow the SFTRS treatment; the second group will receive conventional multi-trauma care.

STUDY POPULATION:

Multi-trauma patients having at least 2 or more injuries of which at least 1 is life threatening, including a) trauma with ISS >= 16, b) complex multiple injuries on both lower extremities, c) a combination of one upper and one lower extremity injury, the latter of which can not be used in load-bearing, or d) complex pelvis/acetabulum fractures.

INTERVENTION:

The Supported Fast-track multi-Trauma Rehabilitation Service (SFTRS) features:
a) The rehabilitation physician from the rehabilitation centre is routinely involved at a very early stage post-trauma. This allows an early start for multidisciplinary rehab treatment.

b) Early transfer (within five days after being added to the waiting list from the rehabilitation centre) to a centralised, specialised trauma rehabilitation unit equipped with facilities for early training programs.

c) Early individual rehabilitation goal setting.

d) Close co-operation and exchange of views and experiences between the trauma surgeon and the rehabilitation team by, for example, monthly clinical sessions and individual patient visits by the trauma surgeon in the first weeks after discharge.

e) Well-documented treatment protocols for multi-trauma patients for both the hospital and rehabilitation centre phases.

Conventional multi-trauma care service (CTCS) is provided in several centres. Multi-trauma

patients are admitted to hospital via the A&E department. After possible surgery, they are transferred to the IC-unit, followed by the hospital's nursing ward, where the patient may stay for several days or weeks. The trauma surgeon, as chief consultant, decides whether or not a rehabilitation physician will be consulted during hospitalisation. Next, ensuing treatment may take place in the hospital's outpatient clinic, in a rehabilitation centre, in a nursing home or with a local GP or physiotherapist. Typically, each of the CTCS stages may have its own more-or-less autonomous treatment perspective, depending on the professional's individual treatment views and experience.

OUTCOME MEASURES:

Primary outcome measures are: quality of life (SF-36) and functional health status (FIM).

Secondary outcome measures are:
anxiety and depression (HADS), cognitive functioning (MMSE) and extent to which individual ADL treatment goals are met (COPM).

Also costs will be assessed (PRODISQ and cost questionnaire).

SAMPLE SIZE CALCULATION AND DATA ANALYSIS:

To detect a difference in FIM score of 4.5 between both services, 71 persons are needed per group. At 15% loss to follow-up, the required group size is 82. For both groups 164 persons are required.
Differences in outcome measures between both groups will be analysed using MANCOVA's.

ECONOMIC EVALUATION:

A cost-utility analysis will be performed from a societal perspective. For the valuation of health care costs and patient & family costs, an update of the Dutch manual for costing in economic evaluations will be used. For care for which no costs-guidelines are available estimations of the costs will be made, based on the real costs and/or on population based estimates from literature. Valuation of production losses will be based on a modification of the friction cost method.

Both generic Quality of life (QoL) and utilities are derived from the SF-36. An overall utility score for population based QoL can be obtained, which facilitates comparisons with other interventions, i.e. the social tariff of the SF-36. Ratios will be determined, based on

incremental costs and effects of SFTRS compared to CTCS. The cost-effectiveness ratio will be stated in terms of costs per improvement on the FIM. The cost-utility ratio will focus on the net cost per QALY gained. Bootstrap re-sampling techniques are used to explore cost-effectiveness uncertainty.

Study objective

It is hypothesised that, from a societal point of view, the Supported Fast track multi-Trauma Rehabilitation Service (SFTRS) is more (cost-)effective relative to the Conventional multi-Trauma Care Service (CTCS).

Study design

- Baseline measurements will be administered as soon as possible post- injury (= T0).

- Further measurements will be taken post-trauma at:

- 3 months (= T1)

- 6 months (T=2)

- 9 months (T=3)

- 12 months (T=4)

Intervention

SFTRS

The Supported Fast-track multi-Trauma Rehabilitation Service (SFTRS) features:

a) The rehabilitation physician from the rehabilitation centre is routinely involved at a very early stage post-trauma. This allows an early start for multidisciplinary rehab treatment.

b) Early transfer (within five days after being added to the waiting list from the rehabilitation centre) to a centralized, specialized trauma rehabilitation unit equipped with facilities for early training programs.

c) Early individual rehabilitation goal setting.

d) Close co-operation and exchange of views and experiences between the trauma surgeon and the rehabilitation team by, for example, monthly clinical sessions and individual patient visits by the trauma surgeon in the first weeks after discharge.

e) Well-documented treatment protocols for multi-trauma patients for both the hospital and rehabilitation centre phases.

Three phases can be identified in the treatment of multi-trauma patients:

1 Early rehabilitation phase

2 Stage II rehabilitation phase

3 Discharge or post-discharge phase

Phase 1:

Early rehabilitation phase
In the early rehabilitation phase, the patient is not allowed to mobilize weight bearing. Consequently, the physiotherapist is concerned with maintaining joint mobility, muscle strength, sitting balance, condition and training transfers as well as treatments with non-weight-bearing conditions such as hydrotherapy and non-weight-bearing gait training. There are 10 sessions per week of 30 minutes each. In addition, fitness, gymnastics, table tennis, swimming, bowling, hand bike, wheelchair training, and archery are given. There are 2-3 sessions per week for each treatment modality of 60 minutes each. The occupational therapist advises on bed posture, mattress types, aids for independent daily self-care, wheelchair-dependency training and meaningful activities that can be performed while bedridden. In addition, the wheelchair accessibility and wheelchair friendliness of the patient¡¯s home are studied. If necessary, written and oral advice on temporary and long-term adaptations to the home is given and support is given and the patient is helped to apply for financial support so that the patient can return home as soon as possible. At first, this would be for a day or two at the weekend, supervised by an occupational therapist, but would later become permanent. With regard to work, the patient¡¯s job is analysed and the patient¡¯s workplace is visited. There are 4 sessions per week of 30 minutes each. The social worker and the psychologist will see every multi trauma patient within the first week after admission. The social worker helps the patient to return home by dealing with the family and offering advice and support to the patient on financial matters, transport facilities. The social worker also contacts the employer and company doctor to look into the possibility of reintegrating the patient into their present job. The psychologist will examine the patient with regard to such things as mood disorders, posttraumatic stress syndrome (PTSS), acceptance problems and cognitive problems. The latter requires extensive neuropsychological testing. In addition, individual and group psychological counselling and specialized treatment for PTSS are given. If necessary, the rehabilitation specialist can refer the patient to a Consultant Psychiatrist, Consultant Neurologist, Consultant Medicine, Consultant Rheumatologist and/or Consultant Urologist, who come to the rehabilitation centre.

Phase 2:

Stage II rehabilitation phase

In the Stage II rehabilitation phase, new treatment aims are added by the physiotherapist. These might include a gradual individual weight bearing scheme, coordination training and functional training. There are 7 therapy sessions per week of 30 minutes. In addition, fitness, gymnastics, table tennis, swimming, rowing, cycling and archery are given. This is offered in 2-4 sessions per week for each treatment modality of 60 minutes each.

The occupational therapist continues with the treatment goals as mentioned for Phase I and trains the patient to perform household tasks, hobbies, etc in a home-like environment. There are three sessions per week of 30 minutes each. In addition, group therapies such as occupational therapy and recreational therapy are given 2-4 times per week each.

The social worker and the psychologist continue the work mentioned in Phase I, depending on the individual needs of each patient.

Phase 3:

(Post) discharge phase
In the discharge phase, the patient is prepared for living at home and is referred to local physiotherapists, specialized sport clubs and mental health care professionals.

CTCS

Conventional multi-trauma care service (CTCS) is provided in several centres. Multi-trauma patients are admitted to hospital via the A&E department. After possible surgery, they are transferred to the IC-unit, followed by the hospital¡¯s nursing ward, where the patient may stay for several days or weeks. The trauma surgeon, as chief consultant, decides whether or not a rehabilitation physician will be consulted during hospitalization. Next, ensuing treatment may take place in the hospital¡¯s outpatient clinic, in a rehabilitation centre, in a nursing home or with a local GP or physiotherapist. Van Vree and co-authors (2001) reported that, typically, each of the CTCS ¡¡ãstages¡¡À might have its own more-or-less autonomous treatment perspective, depending on the professional¡¯s individual treatment views and experience.
The effectiveness of multi-trauma rehabilitation interventions and its constituting elements has been established in numerous studies. Even most recently, Holtslag (2007), in his PhD research, investigated the long-term outcome after major trauma. Furthermore, effectiveness of multi-trauma care has been established by others (e.g. Cameron et al., 2004), as reported in the systematic review (see below). In the group of van Vugt, Frankema and colleagues (2002) have investigated the quality of extamural and intramural trauma care.

Contacts

Public
Scientific Research Co-ordinator
Rehabilitation Foundation Limburg (SRL)
H.A.M. Seelen
Zandbergsweg 111

Hoensbroek 6432 CC
The Netherlands
+31 (0)45 5282221
Scientific
Scientific Research Co-ordinator
Rehabilitation Foundation Limburg (SRL)
H.A.M. Seelen
Zandbergsweg 111

Hoensbroek 6432 CC
The Netherlands
+31 (0)45 5282221

Eligibility criteria

Inclusion criteria

1. Age ≥ 18 yrs

2. Multi-trauma

3. Hospitalisation after A&E admission

4. Rehabilitation indication, i.e. lasting impairments or handicaps are expected

5. Adequate Dutch language skills

Exclusion criteria

1. Alcohol and/or drug abuse

2. Severe psychiatric problems

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	164
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-07-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1333
NTR-old	NTR1391
Other	ZonMw : 17088.2704.
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A