

Calcitonin Gene derived peptides for an Optimized Patient Transfer using an Innovative Multidisciplinary Assessment in the Canton Aargau (OPTIMA II)

Submission date 22/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/12/2020	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<https://optima.mda.ch>

Contact information

Type(s)
Scientific

Contact name
Dr Werner Albrich

Contact details
Kantonsspital Aarau
Aarau
Switzerland
5001

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NA

Study information

Scientific Title

Calcitonin Gene derived peptides for an Optimized Patient Transfer using an Innovative Multidisciplinary Assessment in the Canton Aargau (OPTIMA II): A trial using two separate interlinked designs

Acronym

OPTIMA II

Study objectives

A double biomarker interdisciplinary risk-assessment bundle reduces length of stay without excess adverse events and without patient dissatisfaction.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics committee of the Canton of Aargau approved on the 14th of September 2010 (ref: EK 2010/045)

Study design

Two separate interlinked designs: an experimental (randomised single blind effectiveness trial [primary aim]) and an integrated mixed methods design (secondary aim)

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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Lower Respiratory Tract Infection (LRTI)

Interventions

All patients receive guideline-based, multidisciplinary bundle of clinical, laboratory (PCT), nursing, functional and psychosocial care, enforced with high-intensity and include clinical

(CURB65 and medical stability), biopsychosocial and functional scores, and structured discharge planning while strongly considering patients preferences and current living situation.

Site of care recommendation will be based on the guideline-conform risk algorithm without (control) or with a second biomarker (ProADM) on days 0, 2 and 5 (+/-1).

Sites of care are recommended as follows:

1. High risk: hospital or intensive care
2. Intermediate risk: short hospitalization
3. Low risk: ambulatory care, post-peracute care (home health care, health resort) or a newly designed Nurse-Led Unit (NLU)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Physician-led length of stay during the index hospital exposure

Secondary outcome measures

1. Primary Aim:

1.1. Other measures of resource utilization (different definitions of length of stay including rehospitalisation; treatment changes)

1.2. Adherence to triage algorithms

1.3. Functional status and adverse events (i.e. mortality; rate of complications)

1.4. Patient satisfaction

1.5. Quality of life assessment

1.6. Effective and chargeable costs for treatment path.

Endpoints will be assessed at discharge to non-hospital setting, 30 days and 3 months after admission.

2. Secondary aim:

2.1. Evaluation of the feasibility of an NLU on institutional, patient and nurse outcomes using a mixed methods approach

Overall study start date

27/09/2010

Completion date

26/09/2011

Eligibility

Key inclusion criteria

1. Patients 18 years of age or older

2. Admitted from the community or a nursing home with acute (i.e. symptoms less than 28 days) Lower Respiratory Tract Infection (LRTI) as main diagnosis. LRTI will consist of at least one respiratory symptom (cough, sputum production, dyspnea, tachypnea, pleuritic pain) and one auscultatory finding or systemic inflammatory signs (core body temperature $>38.0^{\circ}\text{C}$, shivers, leukocyte count >10 or $<4 \times 10^9$ cells/L) independent of antibiotic pretreatment.

3. Ability to understand verbal and written instructions and informed consent by patient or available relatives

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

Total final enrolment

313

Key exclusion criteria

1. Patients permanently unable to give written informed consent, e.g. with severe dementia, if no relative and an independent physician (not part of the study team) are available to provide consent for the patient
2. Patients without command of the German, English, French, Italian, Turkish or Serbian language, who will not be able, within reason, to get translators (e.g. family members) during admission, hospitalization and follow-up telephone interview
3. Terminal and very severe disease or medical co-morbidity where death is imminent and comfort therapy is provided
4. Severe immunosuppression, foreseeable non-compliance for follow-up (e.g. current drug use)

Date of first enrolment

27/09/2010

Date of final enrolment

26/09/2011

Locations**Countries of recruitment**

Switzerland

Study participating centre

Kantonsspital Aarau

Aarau

Switzerland

5001

Sponsor information

Organisation

Kantonsspital Aarau (Switzerland)

Sponsor details

Tellstrasse
Aarau
Switzerland
5001

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/056tb3809>

Funder(s)

Funder type

Government

Funder Name

Kantonsspital Aarau (Switzerland) - investigator-driven

Funder Name

Canton Aargau Health Department (Gesundheitsdepartement des Kantons Aargau) - local government grant

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	01/10/2013	18/12/2020	Yes	No