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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

Registration date
26/10/2010

Overall study status
Completed

Last Edited
18/12/2020

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Physician-led length of stay during the index hospital exposure

Key secondary outcome(s))
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

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° C, shivers, leukocyte count >10 or <4 x 109 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/056tb3809

Funder(s)

Funder type
Government

Funder Name

Kantonsspital Aarau (Swizterland) - investigator-driven

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

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes