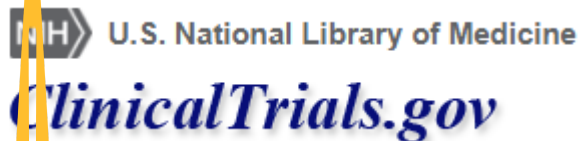


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Reduction the Duration of Antibiotic Therapy in the Elderly (PROPAGE) (PROPAGE)



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT02173613

[Recruitment Status](#) ⓘ : Terminated

[First Posted](#) ⓘ : June 25, 2014

[Last Update Posted](#) ⓘ : May 2, 2022

Sponsor:

University Hospital, Grenoble

Information provided by (Responsible Party):

University Hospital, Grenoble

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Tracking Information	
First Submitted Date ICMJE	June 20, 2013
First Posted Date ICMJE	June 25, 2014
Last Update Posted Date	May 2, 2022
Actual Study Start Date ICMJE	August 2012
Actual Primary Completion Date	December 2015 (Final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE (submitted: June 20, 2014)	Duration of antibiotic therapy [Time Frame: Success of antibiotic therapy within 45 days of inclusion]
Original Primary Outcome Measures ICMJE	<i>Same as current</i>
Change History	Complete list of historical versions of study NCT02173613 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE	<i>Not Provided</i>
Original Secondary Outcome Measures ICMJE	<i>Not Provided</i>
Current Other Pre-	

specified Outcome Measures	<i>Not Provided</i>
Original Other Pre-specified Outcome Measures	<i>Not Provided</i>
Descriptive Information	
Brief Title ICMJE	Reduction the Duration of Antibiotic Therapy in the Elderly (PROPAGE)
Official Title ICMJE	Reduction of the Duration of Antibiotic Guided by Procalcitonin in Infections Lungs of Hospitalized Elderly: a Randomized
Brief Summary	The main objective is to evaluate the interest of the repeated measurement of procalcitonin in patients with pulmonary infection to reduce the duration of antibiotic therapy in comparison with a conventional clinical strategy.
Detailed Description	<i>Not Provided</i>
Study Type ICMJE	Interventional
Study Phase ICMJE	Not Applicable
Study Design ICMJE	Allocation: Randomized Intervention Model: Parallel Assignment Masking: None (Open Label) Primary Purpose: Other
Condition ICMJE	Lung Infection
Intervention ICMJE	Other: procalcitonine The recommendations will be based on the level of PCT: 4 levels of advice will be given: <ul style="list-style-type: none"> • It is highly recommended to stop antibiotics if PCT <0.1ng/ml, and the recommended stop if 0.1ng/ml <PCT <0.25 ng / ml. • It is recommended to continue treatment if 0.25 ng / ml <PCT ng / ml.

	<ul style="list-style-type: none"> Finally, if the initial PCT greater than 10 ng / ml, a stop will be advised in case of reduction to less than 10% of baseline level.
Study Arms <small>ICMJE</small>	<ul style="list-style-type: none"> Experimental: Procalcitonine every 2 days, they will receive the dose of PCT and decide to stop antibiotic treatment according to the algorithm 2. They will notify the results of clinical evaluations in the electronics and all adverse event report forms. Intervention: Other: procalcitonine No Intervention: contrôle Only clinical reassessments will be conducted and documented. Data on antibiotic will be listed and all adverse events. Data on the PCT from D2 to D4, D6, D8 and D15 output or will not be available to the prescriber.
Publications *	<ul style="list-style-type: none"> Polton D, Sermet C. Le vieillissement de la population va-t-il submerger le système de santé ? Bulletin Epidémiologique Hebdomadaire. 2006; 5-6:49-52. Gaymu J. Aspects démographiques du vieillissement; Bulletin Epidémiologique Hebdomadaire. 2006; 5-6:38-9. Fein AM. Pneumonia in the elderly: overview of diagnostic and therapeutic approaches. Clin Infect Dis. 1999 Apr;28(4):726-9. Review. van der Steen JT, Ooms ME, van der Wal G, Ribbe MW. Withholding or starting antibiotic treatment in patients with dementia and pneumonia: prediction of mortality with physicians' judgment of illness severity and with specific prognostic models. Med Decis Making. 2005 Mar-Apr;25(2):210-21. High KP. Infection as a cause of age-related morbidity and mortality. Ageing Res Rev. 2004 Jan;3(1):1-14. Review. El Solh AA, Aquilina AT, Gunen H, Ramadan F. Radiographic resolution of community-acquired bacterial pneumonia in the elderly. J Am Geriatr Soc. 2004 Feb;52(2):224-9. Torres OH, Muñoz J, Ruiz D, Ris J, Gich I, Coma E, Gurguí M, Vázquez G. Outcome predictors of pneumonia in elderly patients: importance of functional assessment. J Am Geriatr Soc. 2004 Oct;52(10):1603-9. Büla CJ, Ghilardi G, Wietlisbach V, Petignat C, Francioli P. Infections and functional impairment in nursing home residents: a reciprocal relationship. J Am Geriatr Soc. 2004 May;52(5):700-6.

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* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.

Recruitment Information	
Recruitment Status ICMJE	Terminated
Actual Enrollment ICMJE (submitted: April 25, 2022)	117
Original Estimated Enrollment ICMJE (submitted: June 20, 2014)	340
Actual Study Completion Date ICMJE	March 2016
Actual Primary Completion Date	December 2015 (Final data collection date for primary outcome measure)
Eligibility Criteria ICMJE	<p>Inclusion Criteria:</p> <ul style="list-style-type: none"> • Age ≥ 80 years • Started antibiotics for a chest infection • Procalcitonin performed J0 antibiotic treatment • Person affiliated to the social security <p>Exclusion Criteria:</p> <ul style="list-style-type: none"> • Patients with a documented infection with germs after Listeria spp, Legionella pneumophilia, Mycobacterium tuberculosis • Patients with a documented infection with a virus or parasite (eg hemorrhagic fever, malaria) • Patients with endovascular infection associated (endocarditis, pacemaker. Intravascular catheter) • Patients with lung abscess associated upon entry Patients with a chronic infection associated • Patients with severe immunosuppression (HIV or transplant)

	<ul style="list-style-type: none"> • Palliative patient • Death within 24 hours of admission to nursing units. • Presence of antibiotic treatment for chronic infection. • Patient under guardianship, curatorship or any other administrative or judicial action or deprivation of the right or freedom • Patients hospitalized without their consent
Sex/Gender <small>ICMJE</small>	Sexes Eligible for Study: All
Ages <small>ICMJE</small>	80 Years and older (Older Adult)
Accepts Healthy Volunteers <small>ICMJE</small>	No
Contacts <small>ICMJE</small>	<i>Contact information is only displayed when the study is recruiting subjects</i>
Listed Location Countries <small>ICMJE</small>	France
Removed Location Countries	
Administrative Information	
NCT Number <small>ICMJE</small>	NCT02173613
Other Study ID Numbers <small>ICMJE</small>	1120
Has Data Monitoring Committee	Yes
U.S. FDA-regulated	<i>Not Provided</i>

Product	
IPD Sharing Statement ICMJE	<i>Not Provided</i>
Current Responsible Party	University Hospital, Grenoble
Original Responsible Party	<u>Same as current</u>
Current Study Sponsor ICMJE	University Hospital, Grenoble
Original Study Sponsor ICMJE	<u>Same as current</u>
Collaborators ICMJE	<i>Not Provided</i>
Investigators ICMJE	Principal Investigator: Gaetan Gavazzi University Clinic of Geriatrics Medicine, Division of Medicine multidisciplinary CHU de Grenoble,
PRS Account	University Hospital, Grenoble
Verification Date	February 2016
ICMJE Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP	