Additional file 1:

| World Health Organization Trial Registration Data Set | |
|---|---|
| Data category | Information |
| Primary registry and trial identifying number | ClinicalTrials.gov |
| | NCT04660084 |
| Date of registration in primary registry | 9 th December, 2020 |
| Secondary identifying numbers | HaukelandUH_31935 |
| Source(s) of monetary or material support | The Research Council of Norway (NORCAP; |
| | 288718) is the primary funder of the trial. |
| | Additional funding support is obtained from the |
| | Trond Mohn Foundation, the University of |
| | Bergen (UiB), and Haukeland University Hospital |
| | (HUH). |
| Primary sponsor | University of Bergen |
| Secondary sponsor(s) | Haukeland University Hospital |
| Contact for public queries | Harleen M.S. Grewal, MD PhD |
| | Email: <u>Harleen.Grewal@uib.no</u> |
| Contact for scientific queries | Harleen M.S. Grewal, MD PhD |
| | Email: <u>Harleen.Grewal@uib.no</u> |
| Public title | Impact of Rapid Molecular Testing on Diagnosis, |
| | Treatment and Management of Community |
| | Acquired Pneumonia in Norway: a pragmatic |
| | randomised controlled trial |
| Scientific title | Impact of Rapid Molecular Testing on Diagnosis, |
| | Treatment and Management of Community |
| | Acquired Pneumonia in Norway: a pragmatic |
| | randomised controlled trial |
| Countries of recruitment | Norway |
| Health condition(s) or problem(s) studied | Respiratory tract infections, community |
| | acquired pneumonia, antibiotic treatment, |
| | rapid diagnostics |
| Intervention(s) | Intervention arm: Samples from the lower |
| | respiratory tract are analysed by the rapid and |
| | comprehensive real-time multiplex PCR panel, |
| | the BioFire [®] FilmArray [®] Pneumonia panel <i>plus</i> |
| | (FAP <i>plus</i>), in addition to standard of care |
| | microbiological methods. |
| | Comparator arm: Samples from the lower |
| | respiratory tract are analysed by standard of |
| | care microbiological methods. |
| Key inclusion and exclusion criteria | Inclusion criteria |
| | Adults (aged ≥18 years) presenting to the |
| | emergency department with a suspicion of CAP |
| | and fulfilling at least two of the following |
| | criteria: new or worsening cough; new or |
| | worsening expectoration of sputum; new or |
| | worsening dyspnoea; haemoptysis; pleuritic |
| | chest pain; radiological evidence of pneumonia; |

| | abnormalities on chest auscultation and/or |
|-------------------------|---|
| | percussion; fever (≥38.0°C). |
| | Written informed consent is needed from the |
| | patient or from their legal guardian/close |
| | relative at the time of recruitment. |
| | Exclusion criteria |
| | Any of the following conditions prohibit |
| | participation in the trial: |
| | - Severe bronchiectasis (defined as patients in |
| | need of regular follow-up and treatment by a |
| | pulmonologist due to bronchiectasis) |
| | - Cystic fibrosis |
| | - A palliative approach (defined as life |
| | expectancy below two weeks) |
| | - Hospitalization within the last 14 days prior to |
| | admission |
| | - Patients not willing or able to provide a lower |
| | respiratory tract sample at admission |
| Study type | Interventional (Clinical Trial) |
| | A pragmatic, single-blind, single-centre |
| | randomised controlled trial |
| | Primary purpose: Diagnostic |
| Date of first enrolment | September 2020 |
| Target sample size | 1060 |
| Beerwitment status | Deve tites |
| Recruitment status | Recruiting |
| Primary outcome(s) | There are two primary outcome variables: |
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| Key secondary outcomes | Treatment with intravenous antibiotics |
|------------------------|--|
| | (within the first seven days after inclusion) |
| | (yes/no) |
| | • Treatment with narrow-spectrum antibiotics |
| | within 48 hours from study inclusion |
| | (yes/no) |
| | De-escalation from broad-spectrum to |
| | narrow-spectrum antibiotics (within the first |
| | Escalation from narrow-spectrum to broad- |
| | spectrum antibiotics (within the first seven |
| | days after inclusion) (yes/no) |
| | • Detected aetiology of CAP (within the first |
| | seven days after inclusion) (yes/no) |
| | Duration of antibiotic use; intravenous and per-oral (in days) |
| | • Duration of intravenous antibiotics (in days) |
| | • Duration of broad-spectrum antibiotics (in |
| | days) |
| | Length of hospital stay (in days) |
| Ethics review | The Regional Committee for Medical and Health |
| | Research Ethics in Southeast Norway approved |
| | the 3 th version of the protocol on 21 st August, |
| | 2020 (registration no.: 31935) |