

primary studies - published RCT

KB001-A, a novel anti-inflammatory, found to be safe and well-tolerated in cystic fibrosis patients infected with *Pseudomonas aeruginosa*.

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Study design (if review, criteria of inclusion for studies)

Randomised controlled mixed-methods pilot study

Participants

CF adults cared for in one large regional CF centre.

Interventions

Participants were randomly allocated 1:1 to the intervention cohort [twice-weekly HM of symptoms measured by the Cystic Fibrosis Respiratory Symptom Diary - Chronic Respiratory Infection Symptom Score (CFRSD-CRISS) and forced expiratory volume in one second (FEV(1))] or a control cohort (routine clinical care) for the 12-month study period.

Outcome measures

Measurements were recorded at study visits at baseline, 3, 6, 9 and 12 months. Spirometry, body weight, comorbidities, medications, hospital inpatient days, courses of antibiotics (oral and intravenous) and PEx (defined by the modified Fuchs criteria) were recorded at each study visit. Health status, capability and cost-effectiveness were measured at each study visit by the Hospital Anxiety and Depression Scale (HADS), the ICEpop CAPability measure for Adults (ICECAP-A), EuroQol 5 dimensions (EQ-5D-5L) questionnaire and an adapted resource use questionnaire. The patient experience of HM was assessed by semi-structured qualitative interviews at baseline and 12 months.

Main results

Eighty-eight participants were recruited, with 44 (50%) randomised to receive HM and 44 (50%) randomised to receive RC. Patient hospital inpatient bed days per annum and overall health-related quality of life were similar between the groups. Protocol-defined PEx requiring intravenous and oral antibiotics were detected more frequently in the HM group, with no other differences between the groups in the secondary outcomes. The total mean National Health Service (NHS) costs were approximately £1500 more per patient for the RC arm than the HM group. The qualitative analysis demonstrated that the patient experience of HM was generally positive and overall the intervention was well accepted

Authors' conclusions

The findings of this trial confirm that HM is effective in detecting PEx in adults with CF. There were no significant differences in hospital inpatient bed days and overall health-related quality of life between the groups. Despite the cost of the HM equipment and the salary of the research fellow to respond to the results, health economics analysis suggests the intervention was less expensive than RC. HM was generally well accepted, with most participants reporting that it resulted in them feeling more empowered and reassured.

<http://dx.doi.org/10.1016/j.jcf.2017.12.006>

See also

J Cyst Fibros. 2018 Jul;17(4):484-491. doi: 10.1016/j.jcf.2017.12.006. Epub 2017 Dec 29.

Keywords

Adult; Child; Home Care Services; non pharmacological intervention - psycho-soc-edu-org; Organization;