primary studies - published RCT

Neonatal screening for cystic fibrosis in Wales and the West Midlands: clinical assessment after five years of screening.

Code: PM1996888 **Year:** 1991 **Date:** 1991 **Author:** Chatfield S

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

RCT. Randomisation method: screening on alternate weeks.

Participants

230,076 screened and 234,510 not screened neonates. Screening from January 1985 to December 1989 in Wales and from January 1985 to October 1989 in the West Midlands. Infants with CF diagnosed by neonatal screening or clinically (alternate weeks). Followed up to age three years. Data available at one, two & three years. Control participants were identified by clinical manifestations of the disease.

Interventions

Type of screening: IRT test followed by a second IRT test when the first IRT test was positive (IRT levels > 900 ng/ml). Continuous oral flucloxacillin versus intermittent antibiotics 'as required'.

Outcome measures

Patients detected by screening and those diagnosed by clinical symptoms alone were assessed annually for differences in clinical, anthropometric, and biochemical variables. Outcomes: weight and height SD scores, carriage rates for P. aeruginosa and S. aureus, chest radiograph scores, lung function tests, number of hospital admissions, number of hospital days, survival and Shwachman score.

Main results

176 CF patients: 86 were in the screened group and 90 in the control group. Number of males and females was not reported. Infants born in the central Birmingham area, those with MI and those with an elder sibling with CF were excluded from analysis. In earlier reports 13 participants with a false-negative screening result were incorrectly analysed as part of the control group. Fifty eight infants not considered to be at risk of cystic fibrosis (they did not present with meconium ileus and do not have a sibling with cystic fibrosis) have been detected by screening and they have been compared with 44 children who were diagnosed clinically. This latter group includes nine children whose screening was negative but who were recognised subsequently to have cystic fibrosis. The mean age at diagnosis of the screened group was significantly lower than that of the group diagnosed clinically. Excluding admissions for diagnostic tests for cystic fibrosis, the screened group spent a significantly shorter time in hospital during the first year of life. The results of all other comparisons made between the screened group and those diagnosed clinically were similar up to the age of 4 years.

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See also

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Keywords

Child; Infant; Neonatal Screening; Newborn; non pharmacological intervention - diagn; screening; diagnostic procedures;