*primary studies - published, non RCT*

# Long-term outcomes of early exposure to repeated general anaesthesia in children with cystic fibrosis (CF-GAIN): a multicentre, open-label, randomised controlled phase 4 trial.

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

Multicentre, randomised, open-label phase 4 trial. This multicentre, randomised, open-label phase 4 trial (CF-GAIN) used the original ACFBAL trial randomisation at 3·6 months (SD 1·6)

### Participants

Children who completed the ACFBAL trial, with a mean age of 5·1 (SD 0·18) years

### Interventions

This trial (CF-GAIN) used the original ACFBAL trial randomisation at 3·6 months (SD 1·6) to BAL-directed therapy or standard-care groups

### Outcome measures

The primary outcome was a composite score of performance on a standardised, computer-based assessment of child attention, processing speed, and response inhibition skills (Conners Continuous Performance test, second edition). Secondary outcomes included intellectual function, other neurobehavioural measures, and brain imaging as an exploratory outcome.

### Main results

At 2 years, the BAL-directed therapy group (n=52) and standard-care group (n=45) had a median of 2·0 (IQR 1·0-3·0) and 0·0 (0·0-0·0) exposures, respectively. At completion of the ACFBAL trial, the BAL-directed therapy group had a median of 6·0 (4·0-9·5) exposures and the standard-care group 2·0 (1·0-4·0) exposures. At CF-GAIN completion, the BAL-directed therapy group had a median of 10·0 (IQR 6·5-14·5) exposures and the standard-care group 4·0 (3·0-7·0) exposures. Cumulative general anaesthesia exposure time was not prospectively collected but, for those with complete cumulative exposure time data to the end of the ACFBAL trial, the median cumulative exposure time for the BAL-directed therapy group (n=29) was 180 (IQR 140-285) min and for the standard-care group (n=32) was 48 (30-122) min. The mean Conners Continuous Performance test, second edition composite score was 51 (SD 8·1) in BAL-directed therapy group and 53 (8·8) in the standard-care group; difference -1·7 (95% CI -5·2 to 1·7; p=0·32) with similar performance on other neurobehavioural measures, including measures of executive function, intellectual quotient scores, and brain imaging.

### Authors' conclusions

The findings suggest that repeated general anaesthesia exposure in young children with cystic fibrosis is not related to functional impairment in attention, intellectual quotient, executive function, or brain structure compared with a group with fewer and shorter cumulative anaesthesia durations.

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### See also

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### Keywords

Anaesthesia; Child; Intraoperative Care; non pharmacological intervention - devices OR physiotherapy; non pharmacological intervention - surg; pharmacological_intervention;