

# Anal fistula plug versus surgeon's preference for surgery for trans-sphincteric anal fistula: the FIAT RCT

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## Plain English summary

### The FIAT RCT

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## Plain English summary

**F**istula-in-ano is a common condition in which the inside of the anus is in communication with the outside skin. It is a cause of long-term suffering owing to recurrent infection. Many surgical operations have been proposed to treat fistula-in-ano, with varying degrees of success. These carry the risk of faecal incontinence. The aim of the Fistula-In-Ano Trial (FIAT) was to assess the benefits of a new technology, the Surgisis® anal fistula plug (Cook Medical, Bloomington, IN, USA), compared with other surgical techniques.

The FIAT involved 304 participants; 152 participants were treated with the fistula plug and 152 participants were treated with an alternative surgical technique. There were no differences in quality of life (QoL) among participants treated with the fistula plug compared with those receiving other treatments when assessed 12 months following the operation. Successful fistula healing was achieved in 54% of fistula plug-treated participants and in 55% of participants treated with an alternative technique at 12 months following the operation. Few patients suffered from faecal incontinence before their operation and there was a slight improvement following treatment with the fistula plug and other surgical treatments. The only difference seen between the group treated with the fistula plug and those receiving other surgical treatments was in the complication rate at the 6-week assessment time, with the fistula plug group having higher rates of unexpected pain.

Economic analysis of the fistula plug compared with the other surgical treatments showed that the fistula plug was more expensive and only produced very small improvements in QoL. On this basis, it is unlikely that decision-makers in the NHS will support the routine use of the fistula plug.

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