



Research Article

Stopping anticoagulation for isolated or incidental pulmonary embolism: the STOPAPE RCT protocol

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Plain language summary

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Pulmonary embolism is a potentially serious condition, whereby blood clots cause a blockage of the blood supply to the lungs. The diagnosis of pulmonary embolism is made with a scan of the lungs, by showing areas where blood cannot get through the vessels easily due to blood clots. The treatment of pulmonary embolism includes anticoagulant medication ('blood thinners') that is taken over months and includes warfarin, an injectable form of heparin and directly acting oral anticoagulants. These medications work by preventing new clots from forming while the body's own mechanisms break down the clots. As the scanning technology for pulmonary embolism has become more sensitive, smaller clots are being diagnosed.

However, small pulmonary embolisms may not cause any symptoms and may be found incidentally on scans performed for other reasons. In these situations, it is unclear whether treatment is required for the pulmonary embolism. These clots in smaller blood vessels away from the centre of the lungs (subsegmental pulmonary embolism) may be removed by the body's own mechanisms for dissolving clots without needing medications. Anticoagulant medication can cause side effects in some patients such as bleeding. For the anticoagulant medication to be appropriate in these smaller pulmonary embolisms, the benefits from preventing future blood clots (pulmonary embolism and deep-vein thrombosis) would need to outweigh the potential risks from the medication side effects. The STOPAPE study aimed to answer this question by testing whether we can safely withhold anticoagulation from patients diagnosed with subsegmental pulmonary embolism.

Although we aimed to enrol 1466 patients in the trial with half getting usual care of anticoagulation and half getting no anticoagulation, we could not recruit patients quickly enough to the trial and, as a result, we could not continue with the STOPAPE study. This study protocol is published to help future research teams that wish to answer this research question.