

The Lung function study.



All welcome!

Contribute to DAN research and make a difference in the diving community. We're inviting anyone who wants to participate to join us on 16 November at Miracle Waters.



Risk/Benefit of PFO Closure

Purpose

The purpose of the study is to establish who is better off: divers with patent foramen ovale (PFO) who undergo closure or divers with PFO who continue diving without the closure. The relative risk estimation will be based on combined incidence of adverse events due to decompression and due to the closure procedure. The risk/benefit estimation will be attempted based on comparison of incidence of decompression sickness (DCS) before the closure with the combined incidence of DCS and adverse events after the closure.

Background

DCS in divers occurs due to the free gas (bubbles) forming in the body during or after decompression from diving. Bubbles may cause injury in the site of origin or in other body tissues if they enter the arterial circulation. Most bubbles are washed out from the site of creation into venous circulation and filtered out by lungs. In divers with PFO some bubbles may pass to the arterial system and cause symptoms of DCS.

The DCS risk in divers with PFO may be three to four times greater than in divers without PFO. The relative risk for DCS in divers with PFO increases with size of the patency and with the severity of the exposure. Some divers with PFO who suffer several episodes of DCS elect to undergo transcatheter PFO closure to reduce the risk of DCS while continuing diving. Some divers with diagnosed PFO continue diving regardless. Justification of PFO closure for divers is highly debated, and data on the risk/benefit of the closure in divers are not available.





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How the Study Works

The trial will enrol 120 qualified participants with annual follow-up over five years. Participants must be 18 years of age or older, be a certified diver with medical clearance for diving, have undergone transcatheter PFO closure in the past five years or have been diagnosed with PFO.

Prior to participation divers will be fully oriented to the study, and those who decide to participate will sign an informed consent form. Participants will complete a diving history questionnaire and provide medical documentation for the diagnosis of PFO and PFO closure. If during the study they undergo more tests and imaging regarding PFO, they will provide the results of those studies to the investigators of this study.

There is no inherent risk associated with participation in the study. Participants will dive according to their own schedule, but they will maintain a log of all their dives during the study, make available all electronic records from their dive computer and or closed-circuit apparatus for research, and report how they feel after each dive. Participants are responsible for maintenance of their dive equipment and for its proper function. It is their responsibility to follow safety procedures deemed necessary for a specific dive circumstances.

