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Titel des Beitrags: Rationale and design of a randomised clinical trial comparing vascular closure device and manual compression to achieve haemostasis after diagnostic coronary angiography: the Instrumental Sealing of ARterial puncture site - CLOSURE device versus manual co
Abstract: Vascular closure devices (VCD) have been introduced into clinical practice with the aim of increasing the procedural efficiency and clinical safety of coronary angiography. However, clinical studies comparing VCD and manual compression have yielded mixed results, and large randomised clinical trials comparing the two strategies are missing. Moreover, comparative efficacy studies between different VCD in routine clinical use are lacking. The Instrumental Sealing of ARterial puncture site - CLOSURE device versus manual compression (ISAR-CLOSURE) trial is a
prospective, randomised clinical trial designed to compare the outcomes associated with the use of VCD or manual compression to achieve femoral haemostasis. The test hypothesis is that femoral haemostasis after coronary angiography achieved using VCD is not inferior to manual compression in terms of access-site-related vascular complications. Patients undergoing coronary angiography via the common femoral artery will be randomised in a 1:1:1 fashion to receive FemoSeal VCD, EXOSEAL VCD or manual compression. The primary endpoint is the incidence of the composite of arterial access-related complications (haematoma>=5 cm, pseudoaneurysm, arteriovenous fistula, access-site-related bleeding, acute ipsilateral leg ischaemia, the need for vascular surgical/interventional treatment or documented local infection) at 30 days after randomisation. According to power calculations based on non-inferiority hypothesis testing, enrolment of 4,500 patients is planned. The trial is registered at www.clinicaltrials.gov (study identifier: NCT01389375). The safety of VCD as compared to manual compression in patients undergoing transfemoral coronary angiography remains an issue of clinical equipoise. The aim of the ISAR-CLOSURE trial is to assess whether femoral haemostasis achieved through the use of VCD is non-inferior to manual compression in terms of access-site-related vascular complications.