|  |  |
| --- | --- |
| **Contact details**  STOP Leg Clots coordinator  Simon Svedman, M.D., PhD-stud.  Tel: +46 76 593 05 50  Email: simon.svedman@ki.se  STOP Leg Clots coordinator  Luigi Belcastro, research nurse  Tel: +46 73 699 48 45  Email: [luigi.belcastro@sll.se](mailto:luigi.belcastro@sll.se)  STOP Leg Clots Primary Investigator  Paul Ackermann, Senior Lecturer, Orthopedic Surgeon  Email: [paul.ackermann@sll.se](mailto:paul.ackermann@sll.se)  **Supported by**  Swedish Orthopedic Traumatology Society (SOTS).  The study is financed by the Swedish Research Council nr: 2017-00202 Web: <https://ki.se/mmk/stop-leg-clots>  **Registration**  The study is registered at clinicaltrials.gov - NCT03259204  <https://clinicaltrials.gov/ct2/show/study/NCT03259204> | **STOP Leg Clots (SLC)**  **Swedish Multicenter Trial of Outpatient**  **Prevention of Leg Clots**  C:\Users\simon\AppData\Local\Microsoft\Windows\INetCache\Content.Word\SLC.PNG  A multicenter study with the aim to assess if addition of mechanical blood clot prevention can reduce the risk leg blood clots and promote healing during leg immobilization  Version 4 – 2020-03-25  <https://ki.se/mmk/stop-leg-clots> |
| **Introduction**  Lower limb immobilization is associated with high risk of complications, i.e. deep venous thrombosis (DVT) as part of venous thromboembolism and failed healing. Pharmacoprophylaxis of DVT has in leg-immobilized patients, however, low effectiveness. Thus, intermittent pneumatic compression (IPC) is an established mechanical DVT-prophylaxis in hospitalized patients. The DVT preventive effect of IPC in leg-immobilized outpatients is, however, not established.  **Research question**  Can addition of mechanical blood clot prophylaxis, with IPC, in leg-immobilized outpatients reduce the risk of DVT and simultaneously promote healing?  **Inclusion criteria**  Male and female patients between the age of 18 - 75 years with an acute injury, Achilles tendon rupture or ankle fracture, which will need leg-immobilization, at least 5 weeks, and that can be treated with an orthosis. Both operatively and non-operatively treated patients can be included. The patient can be included within 10 days from injury.  **Pharmacological thrombosis prophylaxis**  Will be treated according to local routines. Pharmacoprophylaxis is not generally recommended, but can be prescribed after risk assessment, eg. earlier VTE, etc. If pharmacoprophylaxis is given then it should be documented with doses and length of treatment.  **Exclusion criteria**  1. Inability to give informed consent. 2. Inability to follow instructions. 3. Planned follow-up outside the study. 4. Renal failure. 5. Heart failure with pitting oedema. 6. Malignancy. 7. Known haemophilia or thrombophilia 8. Known ongoing thromboembolic event. 9. Pregnancy | **Randomisation/ reporting**  Online via <https://redcap.ki.se/>  Participating clinics will receive login details.  See contact details on the backside of the flyer.  **Treatment time**  Patients randomized to IPC should use the treatment continuously (day/night) when sitting or lying. The minimum recommended treatment time is 10 hours daily. The treatment shall continue until the lower limb immobilization is removed, i.e. around 6-8 weeks.  **Follow-up**  2 weeks: Outpatient visit to check for complications and compliance.  6-8 weeks (completion of leg-immobilization): Duplex ultrasound, check for complications and compliance.  6 months: Online fill in validated questionnaires.  12 months: Online fill in validated questionnaires.  **Number of patients**  1400 patients. 1000 ankle fractures and 400 Achilles tendon ruptures. Analyses will be based on ”intention to treat”.  **Primary outcome**  The presence of a symptomatic / asymptomatic DVT within the time of immobilization. Upon completion of immobilization at approximately 6-8v a screening compression duplex ultrasound is performed. |