



Compression evaluated anno 2016



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Why do we need better scientific proof:

- Trials not enough powered ($\ll n$)
- Compliance bias!!!
 - Because stockings are not worn \rightarrow the outcome is negatively influenced
- Bad designed trials (SOCKS trial)
- Competition between manufacturers.

What scientific proof do we need:

- Compression :
 - Reduces PTS after a DVT
 - Improves symptoms in PTS
 - Improves symptoms in C3,4,5,6
 - Improves outcome after superficial vein treatment.



With scientific proof do we:

- Improve reimbursement
- Improve care
- Improve compliance
- Reduce competition because each piece of the pie is bigger!!



How can we do it:

- ◎ Large randomized controlled trials with sensors!!
 - With sensor in stocking
 - Compression and QoL questionnaires
 - European trial centre (ICC/ECOP)
 - Trial DVT
 - Trial PTS
 - Trial C3,4,5,6
 - Trial posttreatment stocking



method:

● RCTs

- With sensor in stocking
 - 1cm in diameter
 - Attached to every stocking
- Compression and QoL questionnaires
- European trial centre (ICC/ECCoP)
 - Trial DVT
 - Trial PTS
 - Trial C3,4,5,6
 - Trial posttreatment stocking

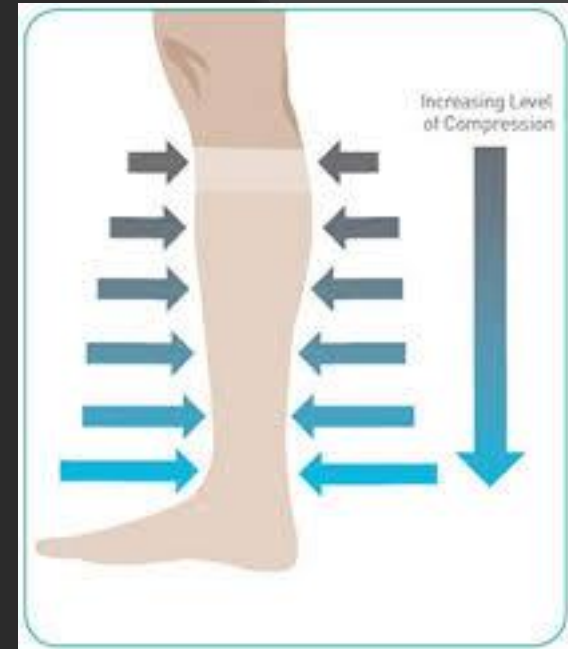


- Gyroscopic
- Accelerometer
- Temperature
- Bluetooth LE
- Offline memory
- Battery

method:

● RCTs

- With sensor in stocking
- Compression and QoL questionnaires
 - All Validated
- European trial centre (ICC/ECOP)
 - Trial DVT
 - Trial PTS
 - Trial C3,4,5,6
 - Trial posttreatment stocking



Veines QoL/Sym
SF 36
Stocking Q

method:

◎ RCTs

- With sensor in stocking
- Compression questionair
- European trial centre (ICC/ECOP)
 - Trial DVT (n=1000)
 - Evaluation after 12 and 24 months
 - Trial PTS
 - Trial C3,4,5,6
 - Trial posttreatment stocking



method:

◎ RCTs

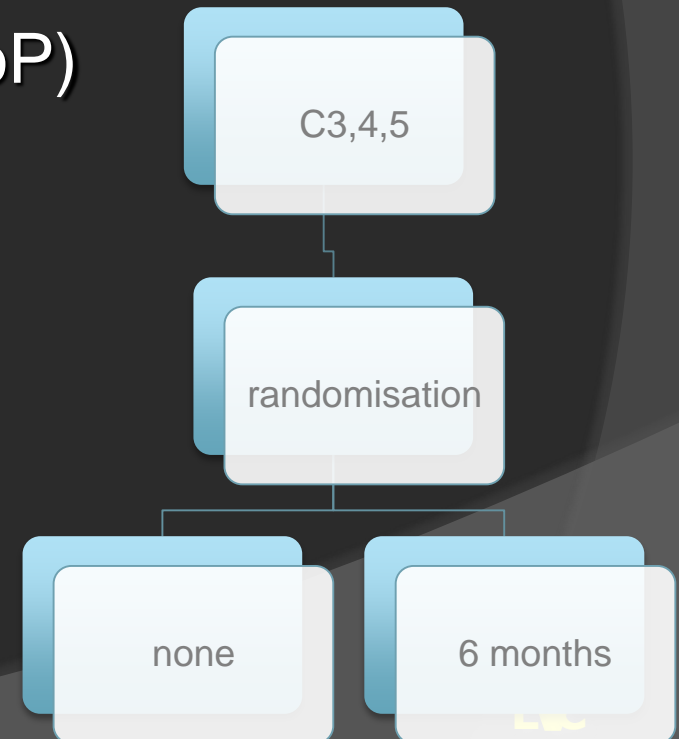
- With sensor in stocking
- Compression questionair
- European trial centre (ICC/ECOP)
 - Trial DVT
 - Trial PTS (n=1000)
 - Evaluation after 6 months
 - Trial C3,4,5,6
 - Trial posttreatment stocking



method:

◎ RCTs

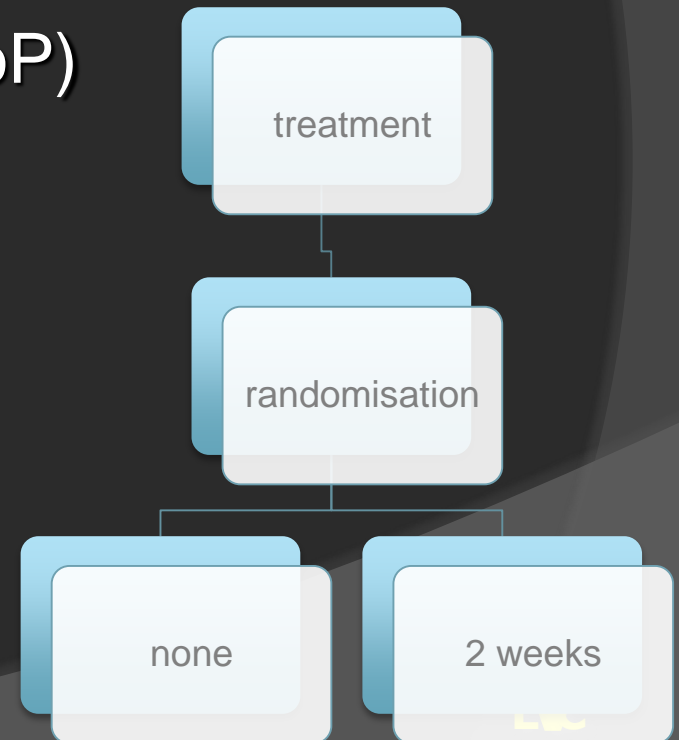
- With sensor in stocking
- Compression questionair
- European trial centre (ICC/ECOP)
 - Trial DVT
 - Trial PTS
 - Trial C3,4,5 (n=1000)
 - Evaluation after 6 months
 - Trial posttreatment stocking



method:

◎ RCTs

- With sensor in stocking
- Compression questionair
- European trial centre (ICC/ECOP)
 - Trial DVT
 - Trial PTS
 - Trial C3,4,5
 - Trial posttreatment stocking
 - N=400
 - Evaluation after 3 months



method:

◎ It will give you data for patients:

- Without stocking
- With stocking but
 - Sensor + (compliant patient)
 - Sensor – (= non compliant patient)

◎ Analyses:

- Without stocking combined with non compliant patient
versus compliant patient
- Show influence of mobilisation and outcome

Logistics:

- Collaboration Maastricht university, ICC and ECoP
- 1 or 2 PhD
 - Organize sensor
 - Organize logistics to get the sensor connected to the stocking
 - Organize the readout
 - Organize the iPad for data (QoL and compression questionnaire registration and readout of the sensor)
 - METC Netherlands and Germany (Maastricht/Aachen)
 - Protocols
 - Monitoring



Costs (4 year period):

● 2 PhD's	540.000
● 1500 sensors (x50 €)	75.000
● Connecting sensors to stocking + readout etc.	100.000
● Trial iPads	150.000
● Secretary (0,5 Fte)	120.000
● Nurse (0,5 Fte)	120.000
● Supervisor (0,1 Fte)	80.000
● Unforeseen	100.000
● Overhead (14%)	180.000
● Total	1.464.000 €



Costs (4/5 year period):

- Total 1.464.000 €
- 2017 464.000
- 2018 300.000
- 2019 300.000
- 2020 300.000
- 2021 100.000
- All compression companies contribute!!
 - Average 150.000 € in 5 years
 - 30.000 € / year / company



Benefit for all companies:

- ◎ >20 publications related to the research
 - 3 trials take only 1-2 years
 - 1 trial takes 3-4 years
- ◎ > 50 presentations in the next 4 years with:
 - Hard data on effectiveness
 - Extra data related to sensor readout.
 - Do patients use the stockings
 - How much do they move
 - Etc. etc.
- ◎ Show the insurance companies that you take it serious
- ◎ Reimbursement improves
- ◎ Etc. etc.



To do or not to do:

?!

A no brainer !!

