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Neuromuscular electrical stimulation for the prevention of venous thromboembolism.  
*Cochrane Database of Systematic Reviews* 2017, Issue 11. Art. No.: CD011764.  
DOI: [10.1002/14651858.CD011764.pub2](https://doi.org/10.1002/14651858.CD011764.pub2).

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[Intervention Review]

# Neuromuscular electrical stimulation for the prevention of venous thromboembolism

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## ABSTRACT

### Background

Venous thromboembolism (VTE) is a serious but preventable cause of morbidity and mortality. Neuromuscular electrical stimulation systems (NMES) for the prevention of VTE may be beneficial for patients in whom pharmacological or standard mechanical prophylaxis methods are contraindicated or are regarded as unsafe or impractical. Although findings of experimental studies suggest that NMES reduce venous stasis, the clinical utility and effectiveness of NMES in VTE prevention remain controversial.

### Objectives

To assess the effectiveness of neuromuscular electrical stimulation in the prevention of venous thromboembolism.

### Search methods

The Cochrane Vascular Group Information Specialist (CIS) searched the Specialised Register (22 March 2017) and the Cochrane Central Register of Controlled Studies (CENTRAL (2017, Issue 2)). The CIS also searched trial registries for details of ongoing and unpublished studies. The review authors searched the bibliographic lists of relevant articles and reviews to look further for potentially eligible trials.

### Selection criteria

We planned to include randomised controlled trials (RCTs) and quasi-randomised trials that compared any form of neuromuscular electrical stimulation as an intervention for VTE prophylaxis (alone or combined with pharmacological or other mechanical methods) versus no prophylaxis and other mechanical or pharmacological methods of VTE prophylaxis.

### Data collection and analysis

At least two independent review authors were involved in study selection, data extraction, methodological quality assessment of included studies, and data analysis. We resolved disagreements by discussion between the two review authors. If no agreement could be reached, a third review author acted as an adjudicator. The main outcomes of the review were total deep vein thrombosis (DVT), symptomatic and asymptomatic DVT, pulmonary embolism (PE), total VTE and bleeding (major and minor). The quality of evidence was assessed using the GRADE approach and is indicated in *italics*.

### Main results

We included in the review five randomised controlled trials and three quasi-randomised trials, enrolling a total of 904 participants. Among these, four studies included patients undergoing major surgical procedures; one study included patients undergoing surgery for hip

fracture under spinal anaesthesia; one study included trauma patients with a contraindication for prophylactic heparin; one study included neurosurgical patients who were operated on under general anaesthesia; and one study included patients with non-functional spinal cord injuries. Overall, eight studies investigated 22 treatment arms. Four studies compared the NMES arm with a no prophylaxis arm, and five studies compared the NMES arm with alternative methods of prophylaxis arms. Alternative methods of prophylaxis included low-dose heparin (5000 IU subcutaneously) - two studies, Dextran 40 - one study, graduated compression stockings (GCS) and intermittent pneumatic compression devices (IPCD) - one study. One study compared combined NMES and low-dose heparin versus no prophylaxis or low-dose heparin alone.

We found no clear difference in risks of total DVT (odds ratio (OR) 1.01, 95% confidence interval (CI) 0.60 to 1.70,  $P = 0.98$ ; 6 studies, 415 participants; *low-quality evidence*), asymptomatic DVT (OR 1.61, 95% CI 0.40 to 6.43,  $P = 0.50$ ; 1 study, 89 participants; *low-quality evidence*), symptomatic DVT (OR 0.40, 95% CI 0.02 to 10.07,  $P = 0.58$ ; 1 study, 89 participants; *low-quality evidence*), PE (OR 1.31, 95% CI 0.38 to 4.48,  $P = 0.67$ ; 2 studies, 126 participants; *low-quality evidence*), and total VTE (OR 0.92, 95% CI 0.34 to 2.52,  $P = 0.88$ ; 1 study, 72 participants; *low-quality evidence*) between prophylaxis with NMES and alternative methods of prophylaxis. None of the studies in this comparison reported bleeding.

Compared with no prophylaxis, NMES showed lower risks of total DVT (OR 0.40, 95% CI 0.23 to 0.70,  $P = 0.02$ ; 4 studies, 576 participants; *moderate-quality evidence*) and total VTE (OR 0.23, 95% CI 0.09 to 0.59,  $P = 0.002$ ; 1 study, 77 participants; *low-quality evidence*). Data show no clear differences in risk of asymptomatic DVT (OR 0.32, 95% CI 0.06 to 1.62,  $P = 0.17$ ; 1 study, 200 participants; *low-quality evidence*), symptomatic DVT (OR 0.06, 95% CI 0.00 to 1.36,  $P = 0.08$ ; 1 study, 160 participants; *low-quality evidence*), or PE (OR 0.36, 95% CI 0.12 to 1.07,  $P = 0.07$ ; 1 study, 77 participants; *low-quality evidence*) between prophylaxis with NMES and no prophylaxis. None of the studies in this comparison reported bleeding.

In comparison with low-dose heparin, NMES was associated with higher risk of total DVT (OR 2.78, 95% CI 1.19 to 6.48,  $P = 0.02$ ; 2 studies, 194 participants; *low-quality evidence*), but data were inadequate for other comparisons (NMES vs Dextran 40, NMES vs GCS, or NMES vs IPCD) and for other clinical outcomes such as symptomatic or asymptomatic DVT, PE, total VTE, and bleeding in individual comparisons.

Overall, we judged the quality of available evidence to be low owing to high or unclear risk of bias and imprecise effect estimates due to small numbers of studies and events.

### Authors' conclusions

Low-quality evidence shows no clear difference in the risk of DVT between NMES and alternative methods of prophylaxis but suggest that NMES may be associated with lower risk of DVT compared with no prophylaxis (*moderate-quality evidence*) and higher risk of DVT compared with low-dose heparin (*low-quality evidence*). The best available evidence about the effectiveness of NMES in the prevention of VTE is not adequately robust to allow definitive conclusions. Adequately powered high-quality randomised controlled trials are required to provide adequately robust evidence.

## PLAIN LANGUAGE SUMMARY

### Neuromuscular electrical stimulation for the prevention of venous thromboembolism

#### Background

Formation of unwanted blood clots in the deep veins of the legs is a serious and potentially fatal health problem because blood clots in the legs can travel to the lungs and cause death. Unwanted blood clots in legs can occur as the result of reduced mobility (due to surgery, stroke, injuries, etc.), increased tendency for blood clotting (due to cancer, inherited conditions, etc.), and other factors. Formation of unwanted blood clots in the legs can be prevented by pharmacological methods (heparin, warfarin, etc.) or mechanical methods (specific stockings or devices that help to compress the legs to promote flow of blood within the veins, reducing the risk of blood clotting). Neuromuscular electrical stimulation systems (NMES) deliver electrical impulses via electrodes to the skin over selected muscle groups or nerves to induce an involuntary muscle contraction. NMES are thought to be effective as a mechanical method of preventing blood clots in the legs. Therefore, we aimed to identify available evidence on the effectiveness of NMES compared with other methods in preventing formation of unwanted blood clots.

#### Study characteristics and key results

We identified eight studies (current until 22 March 2017) enrolling a total of 904 participants that compared NMES with no treatment or with other methods for preventing blood clots, such as low-dose heparin and compression stockings. We found no clear difference in the risk of unwanted blood clots in the legs between NMES and alternative methods of blood clot prevention. We also found that NMES is associated with lower risk of formation of unwanted blood clots in the legs when compared with no treatment, but higher risk of unwanted blood clot formation when compared with heparin. Additional studies are required to obtain stronger evidence.

#### Quality of the evidence

Overall, the quality of available evidence is low and has been downgraded owing to high or unclear risk of bias, differences between studies, and imprecise effect estimates due to small numbers of studies and events.