

# Clinical trials of antithrombotics for superficial thrombophlebitis in superficial thrombophlebitis of the leg

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## 1 acetamin

Trial	Treatments	Patients	Trials design and methods
<b>Oral acetamin vs diclofenac</b>			
Nusser , 1991 n=NA follow-up:	Oral acetamin (60 mg three times daily) for 15 weeks versus diclofenac (50 mg three times daily)	patients with ST	

## References

Nusser, 1991:

## 2 antivitamin K

Trial	Treatments	Patients	Trials design and methods
<b>coumadin vs low dose heparin</b>			
Belcaro (coumadin vs low dose hep) , 1999 n=NA follow-up:	coumadin versus low-dose subcutaneous heparin	-	

## References

Belcaro (coumadin vs low dose hep), 1999:

## 3 defibrotide

Trial	Treatments	Patients	Trials design and methods
<b>defibrotide vs low dose heparin</b>			
Belcaro , 1990 n=NA follow-up:	Defibrotide versus low-dose heparin	with ST	

## References

### Belcaro, 1990:

Belcaro G Evolution of superficial vein thrombosis treated with defibrotide: comparison with low dose subcutaneous heparin. Int J Tissue React 1990;12:319-24 [2098372]

## 4 desmin

Trial	Treatments	Patients	Trials design and methods
<b>desmin 200 vs desmin 100</b>			
Andreozzi (200 vs 100) , 1996 n=NA follow-up:	Dermatan sulfate (Desmin) (100 mg twice s.c.)y8 versus Desmin (100 mg once daily s.c.)	Patients with ST or varicophlebitis of the lower limbs	
<b>desmin SC vs desmin 100</b>			
Andreozzi (desmin SC vs 100) , 1996 n=NA	-	-	

## References

### Andreozzi (200 vs 100), 1996:

Andreozzi GM, Signorelli S, Di Pino L, Martini R, Marchitelli E, Pinto A, Romeo S, Zamboni V, Palazzini E Tolerability and clinical efficacy of desmin in the treatment of superficial thrombovaricophlebitis. Angiology 1996;47:887-94 [8810655]

### Andreozzi (desmin SC vs 100), 1996:

## 5 Enzyme therapy

Trial	Treatments	Patients	Trials design and methods
<b>Wobenzym vs placebo</b>			
Koshkin , 2001 n=NA follow-up:	Systemic enzyme therapy (Wobenzym) (10 tablets 3 times daily) for 16 days versus placebo	with acute ST	
Marshall , 2001 n=NA follow-up:	Wobenzym (4 tablets 3 times daily)for 12-16 days versus placebo	with acute ST of the leg	

## References

### Koshkin, 2001:

Marshall, 2001:

## 6 Essaven

Trial	Treatments	Patients	Trials design and methods
<b>Essaven vs placebo</b>			
De Sanctis , 2001 n=NA follow-up:	Essaven gel (5 cm of gel) for 4 weeks versus placebo	patients with superficial thrombophlebitis and varicose veins	
Incandela , 2001 n=NA follow-up:	Essaven gel (5 cm of gel) versus placebo	patients with ST associated with varicesm	

## References

De Sanctis, 2001:

Incandela, 2001:

Incandela L, De Sanctis MT, Cesarone MR, Ricci A, Errichi BM, Dugal M, Belcaro G, Griffin M Treatment of superficial vein thrombosis: clinical evaluation of Essaven gel—a placebo-controlled, 8-week, randomized study. *Angiology* 2001;52 Suppl 3:S69-72 [[11775653](#)]

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## 7 Etofenak

Trial	Treatments	Patients	Trials design and methods
<b>Etofenak vs diclofenac</b>			
Holzgreve , 1989 n=NA follow-up:	Etofenak gel versus diclofenac gel	patientst with superficial venous thrombosis	

## References

Holzgreve, 1989:

## 8 Exhirud

Trial	Treatments	Patients	Trials design and methods
<b>Exhirud ointment vs placebo</b>			
Nocker (exhirud) , 1991 n=NA	-	-	

## References

Nocker (exhirud), 1991:

## 9 Fixed-dose LMWH

Trial	Treatments	Patients	Trials design and methods
<b>LMWH vs heparin spraygel</b>			
Gorski (LMWH vs hep spraygel) , 2005 n=NA	-	-	
Katzenschlager (LMWH vs hep spraygel) , 2003 n=NA	-	-	
<b>nadroparin fixed-dose vs nadroparin weight-adjusted</b>			
Vesalio , 2005 n=NA follow-up:	LMWH (nadroparin) body-weight adjusted (full dose for 10 days followed by half dose for 20 additional days) versus nadroparin (2850 anti-Xa IU) for 30 days	patients with superficial vein thrombosis of the great saphenous vein with the thrombosis extending up to 3 cm from the sapheno-femoral junction	
<b>nadroparin vs naproxene</b>			
Titon (nadroparin 0.6ml vs naproxen) , 1994 n=NA follow-up:	nadroparin (s.c. 0.6 ml for 6150 IU anti-Xa once daily) j versus Naproxene (oral 500 mg once daily)	patients with ST	
Titon (nadroparin 61.5 IU anti-Xa/kg vs naproxen) , 1994 n=NA follow-up:	nadroparin (s.c. 0.6 ml for 6150 IU anti-Xa once daily) j versus Naproxene (oral 500 mg once daily)	patients with ST	
<b>Fixed-dose LMWH vs NSAIDs</b>			
STENOX (enox fixed dose vs NSAIDs) , 2003 n=NA	-	-	

## References

Gorski (LMWH vs hep spraygel), 2005:

Katzenschlager (LMWH vs hep spraygel), 2003:

Vesalio, 2005:

Prandoni P, Tormene D, Pesavento R High vs. low doses of low-molecular-weight heparin for the treatment of superficial vein thrombosis of the legs: a double-blind, randomized trial. J Thromb Haemost 2005;3:1152-7 [15946202]

Titon (nadroparin 0.6ml vs naproxen), 1994:

Titon (nadroparin 61.5 IU anti-Xa/kg vs naproxen), 1994:

### STENOX (enox fixed dose vs NSAIDS), 2003:

A pilot randomized double-blind comparison of a low-molecular-weight heparin, a nonsteroidal anti-inflammatory agent, and placebo in the treatment of superficial vein thrombosis. Arch Intern Med 2003 Jul 28;163:1657-63 [[12885680](#)]

## 10 fondaparinux

Trial	Treatments	Patients	Trials design and methods
<b>fondaparinux vs placebo</b>			
<b>CALISTO , 2010</b> [NCT00443053] n=1502/1500 follow-up: 45 days (77d)	fondaparinux 2.5mg up to 45 days versus placebo	patients with acute symptomatic isolated superficial thrombophlebitis of the lower limbs	Parallel groups double blind 17 countries

### References

#### CALISTO, 2010:

Bauersachs R., Dcousus H., Prandoni P., Leizorovicz A., For the CALISTO Investigators Fondaparinux 2.5 mg for the treatment of superficial vein thrombosis (SVT): the randomized double-blind placebo-controlled CALISTO trial in 3002 patients

Decousus H, Prandoni P, Mismetti P, Bauersachs RM, Boda Z, Brenner B, Laporte S, Matyas L, Middeldorp S, Sokurenko G, Leizorovicz A Fondaparinux for the treatment of superficial-vein thrombosis in the legs. N Engl J Med 2010 Sep 23;363:1222-32 [[20860504](#)] [10.1056/NEJMoa0912072](#)

## 11 Heparansulphate

Trial	Treatments	Patients	Trials design and methods
<b>Heparansulphate vs sulodexide</b>			
<b>Messa , 1997</b> n=NA follow-up:	Heparansulphate (100 mg 3 times daily orally) for 2 weeks versus sulodexide (250 LSU twice daily, orally)	patients with ST	

### References

#### Messa, 1997:

Messa G, La Placa G, Puccetti L, Di Perri T [Effectiveness and tolerability of heparan sulfate in the treatment of superficial thrombophlebitis. Controlled clinical study vs sulodexide] Minerva Cardioangiol 1997;45:147-53 [[9213829](#)]

## 12 heparin SC

Trial	Treatments	Patients	Trials design and methods
<b>heparin vs</b>			
Belcaro (hep vs defibrotide) , 1990 n=NA	-	-	
<b>heparin vs no treatment</b>			
Belcaro (hep vs no hep) , 1989	-	-	
n=NA			

## References

Belcaro (hep vs defibrotide), 1990:

Belcaro (hep vs no hep), 1989:

## 13 heparin spraygel

Trial	Treatments	Patients	Trials design and methods
<b>heparin spraygel vs clexane</b>			
Gorski , 2005 n=NA follow-up:	Topical liposomal heparin spraygel (4 puffs of 458 IU three times daily) versus clexane (40 mg once daily)	patients with symptomatic superficial venous thrombosis confirmed by ultrasonography with first symptoms not earlier than 72 hours	
<b>liposomal heparin-spraygel vs enoxaparin</b>			
Katzenschlager , 2003 n=NA follow-up:	Topical liposomal heparin-spraygel (lipohep 2400 IU/g, 4 spray puffs three times daily) for 7-14 days versus enoxaparin (40 mg s.c.) for 7-14 days	with ST diagnosed by ultrasound with signs and symptoms lasting less than 72 hours(daily)o	

## References

Gorski, 2005:

Grski G, Szopinski P, Michalak J, Marianowska A, Borkowski M, Geremek M, Trochimczuk M, Brotnek J, Srnk S, Semnka J, Wilkowski D, Noszczyk W Liposomal heparin spray: a new formula in adjunctive treatment of superficial venous thrombosis. *Angiology* 2005;56:9-17 [[15678251](#)]

Katzenschlager, 2003:

## 14 High-dose UFH

Trial	Treatments	Patients	Trials design and methods
<b>heparin vs low dose UFH</b>			
Marchiori , 2002 n=NA follow-up:	UFH (s.c. 12500 IU for one week then 10000 IU) for 4 weeks versus UFH (5000 IU)	patients with ST of the great saphenous vein	

## References

### Marchiori, 2002:

Marchiori A, Verlato F, Sabbion P, Camporese G, Rosso F, Mosena L, Andreozzi GM, Prandoni P High versus low doses of unfractionated heparin for the treatment of superficial thrombophlebitis of the leg. A prospective, controlled, randomized study. Haematologica 2002;87:523-7 [[12010667](#)]

## 15 Nimesulide

Trial	Treatments	Patients	Trials design and methods
<b>Nimesulide vs diclofenac</b>			
Ferrari , 1992 n=NA follow-up:	Nimesulide 100 mg twice dailyitm versus diclofenac sodium 50 mg twice daily for 10 days	with acute ST	

## References

### Ferrari, 1992:

Ferrari E, Pratesi C, Scaricabarozzi I, Trezzani R [Clinical study of the therapeutic efficacy and tolerance of nimesulide in comparison with a sodium diclofenac in the treatment of acute superficial thrombophlebitis] Minerva Cardioangiol 1992;40:455-60 [[1291926](#)]

## 16 NSAIDs

Trial	Treatments	Patients	Trials design and methods
<b>Diclofenac vs placebo</b>			
Nocker (diclofenac) , 1991 n=NA follow-up:	Diclofenac gel (1 g diclofenac/100 g gel) for 3 weeks versus placebo	patients with unilateral thrombophlebitis of the legs	
<b>Indomethacin vs placebo</b>			
Anonymous , 1970 n=NA follow-up:	Indomethacin 50mg 3 times daily for 1 week versus placebo	patients with superficial thrombophlebitis of calf and/or thigh	Parallel groups double blind

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Trial	Treatments	Patients	Trials design and methods
<b>Oxyphenbutazone vs placebo</b>			
Archer , 1977 n=NA follow-up:	Oxyphenbutazone 100 mg 4 times daily for 7 days versus placebo	patients with superficial thrombophlebitis	Parallel groups open
<b>tenoxicam vs placebo</b>			
STENOX (tenoxicam vs PBO) , 2003 n=NA follow-up:	oral tenoxicam (20 mg) for 8-12 days versus placebo	-	

## References

**Nocker (diclofenac), 1991:**

**Anonymous, 1970:**

Archer DS, Fowler PD Comparison of oxyphenbutazone and placebo in the treatment of superficial thrombophlebitis: an object lesson in clinical trial design. Practitioner 1977;218:712-5 [329257]

Indomethacin in superficial thrombophlebitis. Practitioner 1970;205:369-72 [4922059]

**Archer, 1977:**

Archer DS, Fowler PD Comparison of oxyphenbutazone and placebo in the treatment of superficial thrombophlebitis: an object lesson in clinical trial design. Practitioner 1977;218:712-5 [329257]

**STENOX (tenoxicam vs PBO), 2003:**

A pilot randomized double-blind comparison of a low-molecular-weight heparin, a nonsteroidal anti-inflammatory agent, and placebo in the treatment of superficial vein thrombosis. Arch Intern Med 2003 Jul 28;163:1657-63 [12885680]

## 17 Prophylactic LMWH

Trial	Treatments	Patients	Trials design and methods
<b>LMWH vs low dose heparin</b>			
Belcaro (LMWH vs low dose hep) , 1999 n=NA follow-up:	LMWH versus low-dose subcutaneous heparin	Patients with ST and large varicose veins	
<b>Prophylactic LMWH vs NSAIDs</b>			
STENOX (prophylactic LMWH vs NSAIDs) , 2003 n=NA	-	-	
<b>enoxaparin vs placebo</b>			

continued...



Trial	Treatments	Patients	Trials design and methods
<b>STENOX (enoxaparin 1.5mg/hg) , 2003</b> n=NA follow-up:	enoxaparin (s.c. 1.5 mg/kg)for 8-12 days versus placebo	patients with St of at least 5 cm on ultrasonography examination	
<b>Stenox (enoxaparin 40mg) , 2003</b> n=NA follow-up:	LMWH (enoxaparin) (s.c. 40 mg) for 8-12 days versus placebo.	patients with ST of at least 5 cm on ultrasonography examination	

## References

### Belcaro (LMWH vs low dose hep), 1999:

Belcaro G, Nicolaidis AN, Errichi BM, Cesarone MR, De Sanctis MT, Incandela L, Venniker R Superficial thrombophlebitis of the legs: a randomized, controlled, follow-up study. *Angiology* 1999;50:523-9 [10431991]

### STENOX (prophylactic LMWH vs NSAIDs), 2003:

A pilot randomized double-blind comparison of a low-molecular-weight heparin, a nonsteroidal anti-inflammatory agent, and placebo in the treatment of superficial vein thrombosis. *Arch Intern Med* 2003 Jul 28;163:1657-63 [12885680]

### STENOX (enoxaparin 1.5mg/hg), 2003:

### Stenox (enoxaparin 40mg), 2003:

A pilot randomized double-blind comparison of a low-molecular-weight heparin, a nonsteroidal anti-inflammatory agent, and placebo in the treatment of superficial vein thrombosis. *Arch Intern Med* 2003;163:1657-63 [12885680]

## 18 Prophylactic UFH

Trial	Treatments	Patients	Trials design and methods
<b>Prophylactic UFH vs no treatment</b>			
<b>Belcaro (prophylactic UFH vs no) , 1999</b> n=NA	-	-	

## References

### Belcaro (prophylactic UFH vs no), 1999:

## 19 surgery

Trial	Treatments	Patients	Trials design and methods
<b>complete stripping vs low dose heparin</b>			

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Trial	Treatments	Patients	Trials design and methods
Belcaro (complete stripping vs low dose hep) , 1999 n=NA follow-up:	surgery (complete stripping) versus low-dose subcutaneous heparinitm	-	
<b>ligation vs low dose heparin</b>			
Belcaro (ligation vs low dose hep) , 1999 n=NA follow-up:	ligation versus low-dose subcutaneous heparin	-	

## References

Belcaro (complete stripping vs low dose hep), 1999:

Belcaro (ligation vs low dose hep), 1999:

## 20 Therapeutic LMWH

Trial	Treatments	Patients	Trials design and methods
<b>enoxaparin vs placebo</b>			
STENOX (enoxaparin 1.5mg/hg) , 2003 n=NA follow-up:	enoxaparin (s.c. 1.5 mg/kg)for 8-12 days versus placebo	patients with St of at least 5 cm on ultrasonography examination	
Stenox (enoxaparin 40mg) , 2003 n=NA follow-up:	LMWH (enoxaparin) (s.c. 40 mg) for 8-12 days versus placebo.	patients with ST of at least 5 cm on ultrasonography examination	
<b>Therapeutic LMWH vs saphenofemoral disconnection</b>			
Lozano , 2003 n=NA follow-up:	Enoxaparin 1mg/kg twice daily for the first week, then 1mg/kg for 3 weeks versus saphenofemoral disconnection	patients with saphenous proximal thrombophlebitis	

## References

STENOX (enoxaparin 1.5mg/hg), 2003:

Stenox (enoxaparin 40mg), 2003:

A pilot randomized double-blind comparison of a low-molecular-weight heparin, a nonsteroidal anti-inflammatory agent, and placebo in the treatment of superficial vein thrombosis. Arch Intern Med 2003;163:1657-63 [[12885680](#)]

Lozano, 2003:

Lozano FS, Almazan A Low-molecular-weight heparin versus saphenofemoral disconnection for the treatment of above-knee greater saphenous thrombophlebitis: a prospective study. Vasc Endovascular Surg 2003;37:415-20 [[14671696](#)]

## 21 thrombectomy

Trial	Treatments	Patients	Trials design and methods
<b>thrombectomy plus ECB vs ECB</b>			
Belcaro , 1989 n=NA follow-up:	Superficial thrombectomy plus ECBp, imag versus ECB alone	Patients with ST without DVT	

### References

#### Belcaro, 1989:

Belcaro G, Errichi BM, Laurora G, Cesarone MR, Candiani C Treatment of acute superficial thrombosis and follow-up by computerized thermography. Vasa 1989;18:227-34 [2678804]

## 22 Topical methylthioadenosine

Trial	Treatments	Patients	Trials design and methods
<b>Topical methylthioadenosine vs placebo</b>			
Pinto , 1992 n=NA follow-up:	Topical 5-methylthioadenosine 0.5% (0.1 ml/cm skin 3 times/day) for 1 week versus placebo	patients with superficial phlebitis	

### References

#### Pinto, 1992:

## 23 Vasotonin

Trial	Treatments	Patients	Trials design and methods
<b>Vasotonin forte vs placebo</b>			
Kuhlwein , 1985 n=NA follow-up:	Vasotonin forte for 3 weeks versus placebo	patients with ST	

### References

#### Kuhlwein, 1985:

## 24 Weight-adjusted LMWH

Trial	Treatments	Patients	Trials design and methods
<b>nadroparin vs naproxene</b>			
Titon (nadroparin 0.6ml vs naproxen) , 1994 n=NA follow-up:	nadroparin (s.c. 0.6 ml for 6150 IU anti-Xa once daily)j versus Naproxene (oral 500 mg once daily)	patients with ST	
Titon (nadroparin 61.5 IU anti-Xa/kg vs naproxen) , 1994 n=NA follow-up:	nadroparin (s.c. 0.6 ml for 6150 IU anti-Xa once daily)j versus Naproxene (oral 500 mg once daily)	patients with ST	

## References

Titon (nadroparin 0.6ml vs naproxen), 1994:

Titon (nadroparin 61.5 IU anti-Xa/kg vs naproxen), 1994:

## 25 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

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