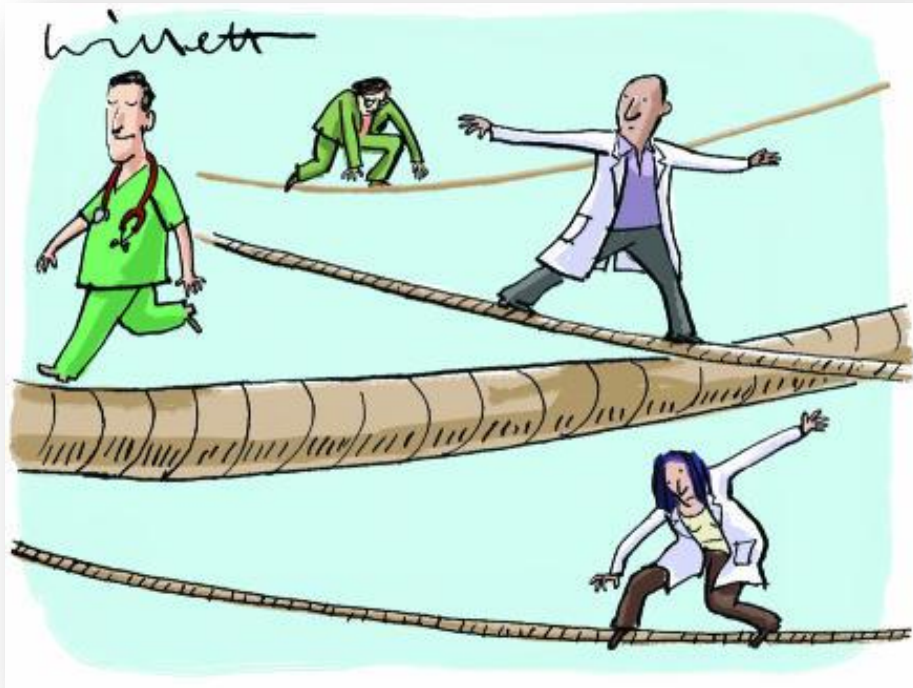




Diyabetik Ayakta Hiperbarik Oksijen Tedavisi

Güncel kanıtlar



MESUT MUTLUOĞLU

GATA Haydarpaşa Eğitim Hastanesi
Sualtı Hekimliği Ve Hiperbarik Tıp Servisi



**IV. UDAIS 5-7 MAYIS 2016,
ISTANBUL**

Diyabetik Ayakta Hiperbarik Oksijen Tedavisi

Güncel Kanıtlar

UHMS

UHM 2015, VOL. 42, NO. 3 - CLINICAL PRACTICE GUIDELINE FOR HBO₂ TO TREAT DFU

A clinical practice guideline for the use of hyperbaric oxygen therapy in the treatment of diabetic foot ulcers

CPG Authors: Enoch T. Huang, Jaleh Mansouri, M. William Tettelbach, Eugene R. Worth

UHMS CPG Oversight Committee: Enoch T. Huang, Jaleh Mansouri, Richard Moon, M. Hassan Murad

CORRESPONDING AUTHOR: Dr. Enoch T. Huang

IV. UDAIS 5-7 MAYIS 2016, ISTANBUL

IWGDF

DIABETES/METABOLISM RESEARCH AND REVIEWS
Diabetes Metab Res Rev 2016; 32(Suppl. 1): 45-74
Published online in Wiley Online Library (wileyonlinelibrary.com)

IWGDF guidance on the diagnosis and treatment of foot infections in persons with diabetes

IV. UDAIS 5-7 MAYIS 2016, ISTANBUL



IDSA

2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections^a

^a C. Pile,¹ Edgar J. G. Peters,¹ David G. Armstrong,² Michael S. Pinzur,¹¹ and Eric Senneville¹²
¹ Health Care System, Seattle; ² Bone Infection Unit, Nuffield Institute for Health, University of Washington, Veterans Affairs Puget Sound Health Care System, Seattle; ³ Bone Infection Unit, Nuffield Institute for Health, University of Washington, Veterans Affairs Puget Sound Health Care System, Seattle; ⁴ MetroHealth Medical Center, Cleveland, Ohio; ⁵ Department of Southern Arizona Limb Salvage Alliance, Department of Surgery, University of Arizona, Tucson, Arizona; ⁶ Department of Surgery, University of Medicine, University of Manitoba, Winnipeg, Manitoba, Canada; ⁷ Department of Surgery, University of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania; ⁸ Department of Medicine, University of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania; ⁹ Department of Medicine, University of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania; ¹⁰ Department of Medicine, University of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania; ¹¹ Department of Medicine, University of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania; ¹² Department of Medicine, University of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania.



10th ECHM Consensus Conference on Hyperbaric Medicine

April 15-16th 2016

Lille

www.echm-lille-consensus-2016.org



IV. UDAIS 5-7 MAYIS 2016, ISTANBUL



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CORRESPONDING AUTHOR: Dr. Enoch T. Huang – enoch.huang@mac.com

GRADE

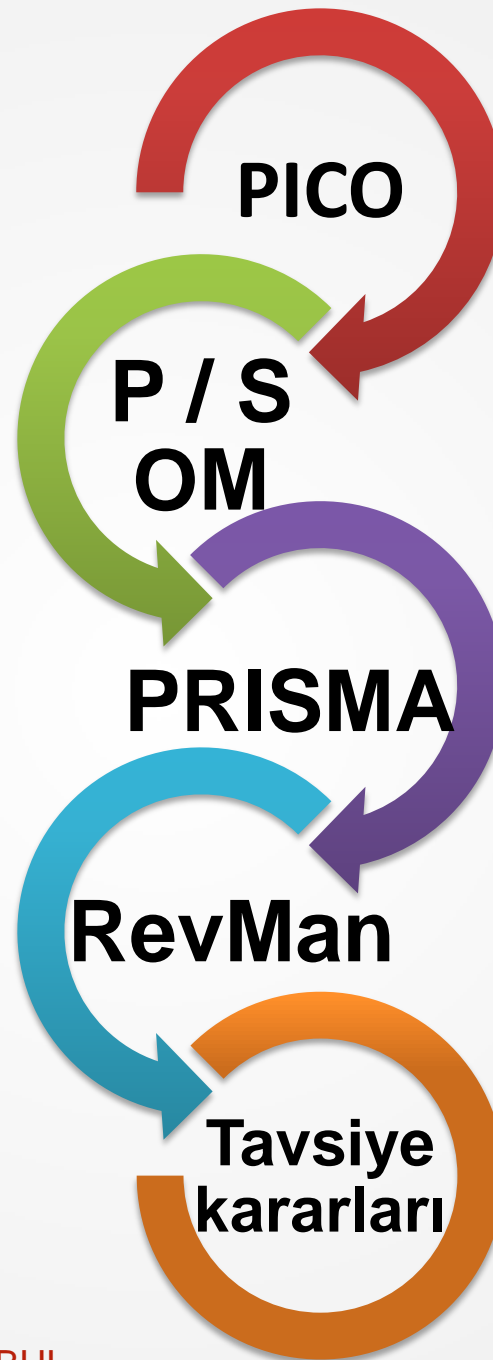
➤ **G**rating

➤ **R**ecommendations

➤ **A**ssessment

➤ **D**evelopment

➤ **E**valuation



- Patient
- Intervention
- Comparison
- Outcome

- Birincil sonuç ölçütleri
- İkincil sonuç ölçütleri

- Literatür taraması & kalite kontrol

- Meta-analiz

- Leyhte
- Aleyhte
- Güçlü
- Şartlı

Wagner sınıflandırması

□ Wagner grade 0



□ Wagner grade 1



□ Wagner grade 2



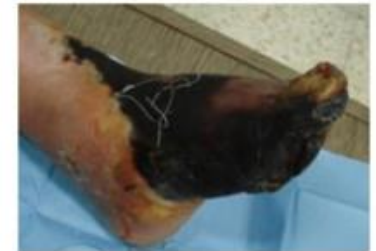
□ Wagner grade 3



□ Wagner grade 4

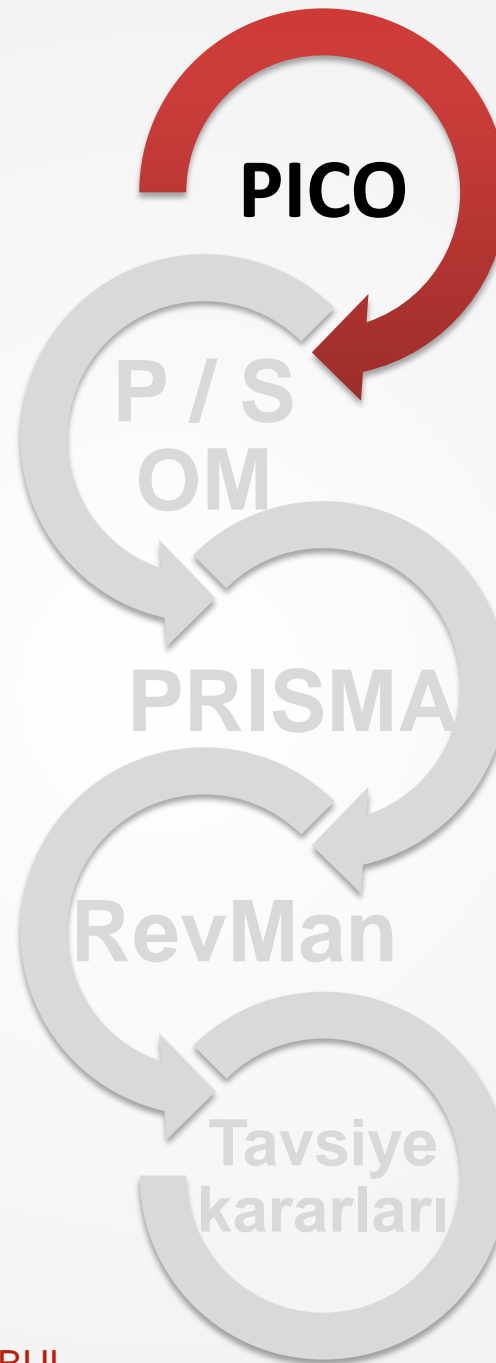


□ Wagner grade 5



Wagner FW, 1981

GRADE



- Patient
- Intervention
- Comparison
- Outcome

- Birincil sonuç ölçütleri
- İkincil sonuç ölçütleri

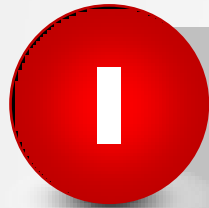
- Literatür taraması

- Meta-analiz

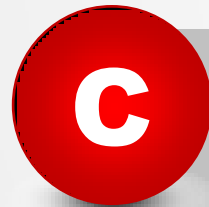
- Lehte
- Aleyhte
- Güçlü
- Şartlı



Patient / Hasta



Intervention / Müdahale



Comparison / Karşılaştırma



Outcome / Sonuç





p

Population

- Diyabetik ayak
- Wagner 1-5

Intervention

- Standart tedavi
- HBOT

1

I

Comparison

- Standart tedavi

Outcome

- Majör amputasyon
- Tam iyileşmeme (1 yıl)
- Enfeksiyonun gerilemesi
- Hayat kalitesi
- Minör amputasyon

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Population

- Diyabetik ayak
- Wagner 1-2
- 30 günlük standart tedavi X

Intervention

- Standart tedavi
- HBOT

Comparison

- Standart tedavi

Outcome

- Majör amputasyon
- Tam iyileşmeme (1 yıl)
- Enfeksiyonun gerilemesi
- Hayat kalitesi
- Minör amputasyon

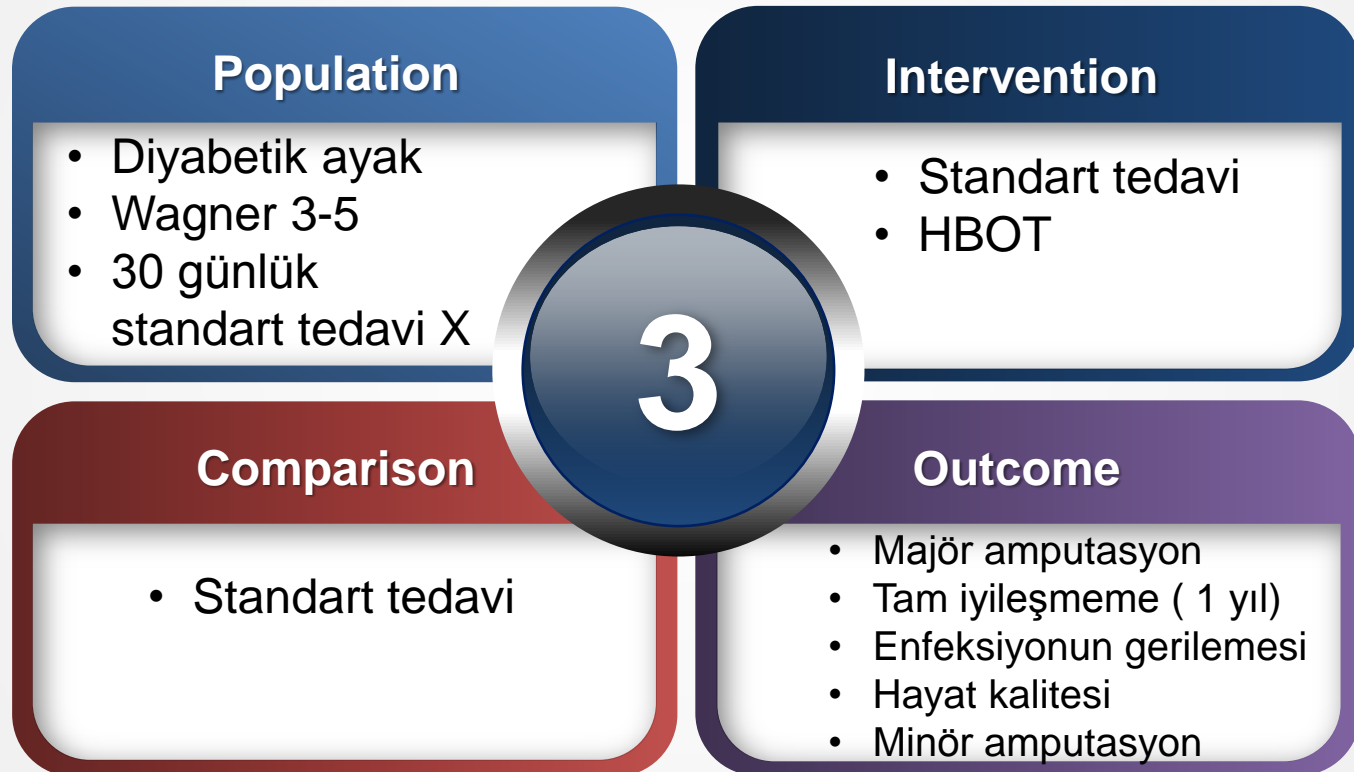
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Population

- Diyabetik ayak
- Wagner 3-5
- Cerrahi / Debritleme

Intervention

- Standart tedavi
- HBOT

4

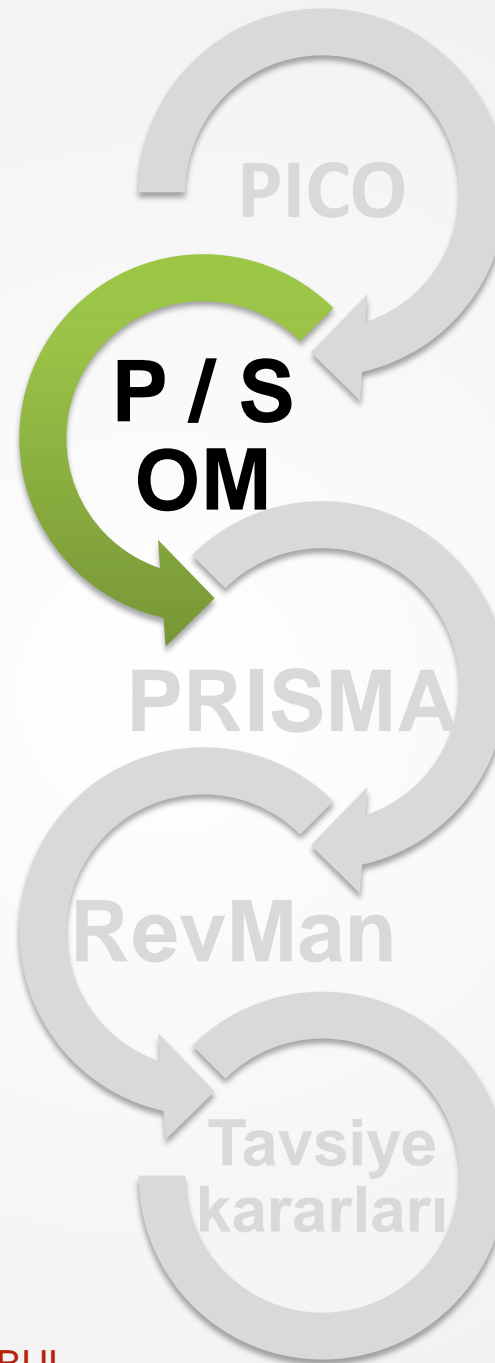
Comparison

- Standart tedavi

Outcome

- Majör amputasyon
- Tam iyileşmeme (1 yıl)
- Enfeksiyonun gerilemesi
- Hayat kalitesi
- Minör amputasyon

GRADE



- Patient
- Intervention
- Comparison
- Outcome

- Birincil sonuç ölçütleri
- İkincil sonuç ölçütleri

- Literatür taraması

- Meta-analiz

- Lehte
- Aleyhte
- Güçlü
- Şartlı

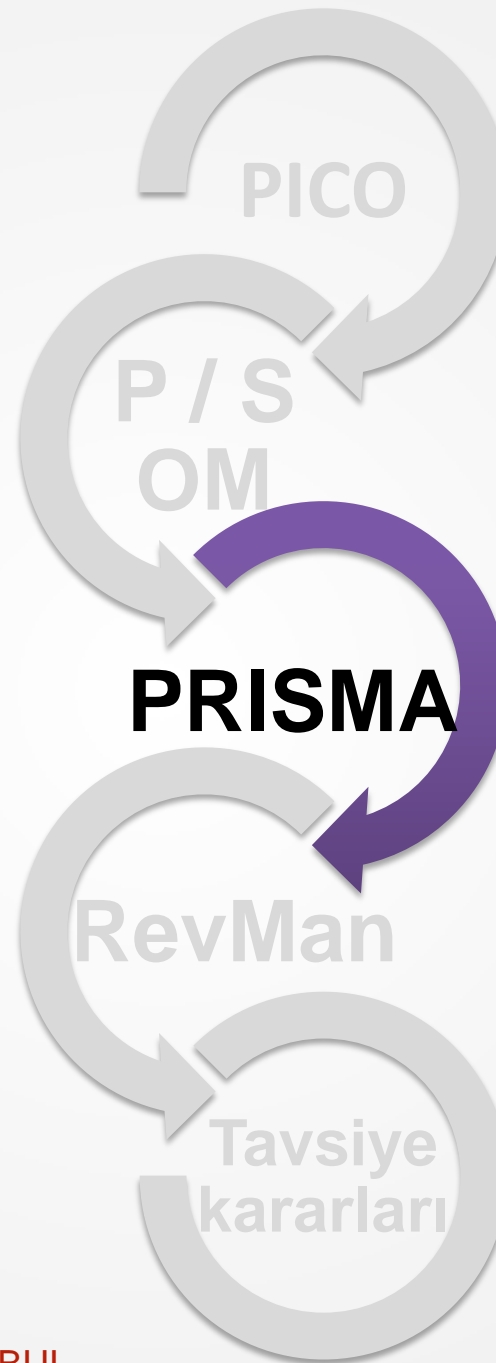
Birincil sonuç ölçütleri

- Majör amputasyon
- Bir yılın sonunda tam iyileşmeme

İkincil sonuç ölçütleri

- Enfeksiyonun gerilemesi
- Hayat kalitesi
- Minör amputasyon

GRADE



- Patient
- Intervention
- Comparison
- Outcome

- Birincil sonuç ölçütleri
- İkincil sonuç ölçütleri

- Literatür taraması & kalite kontrol

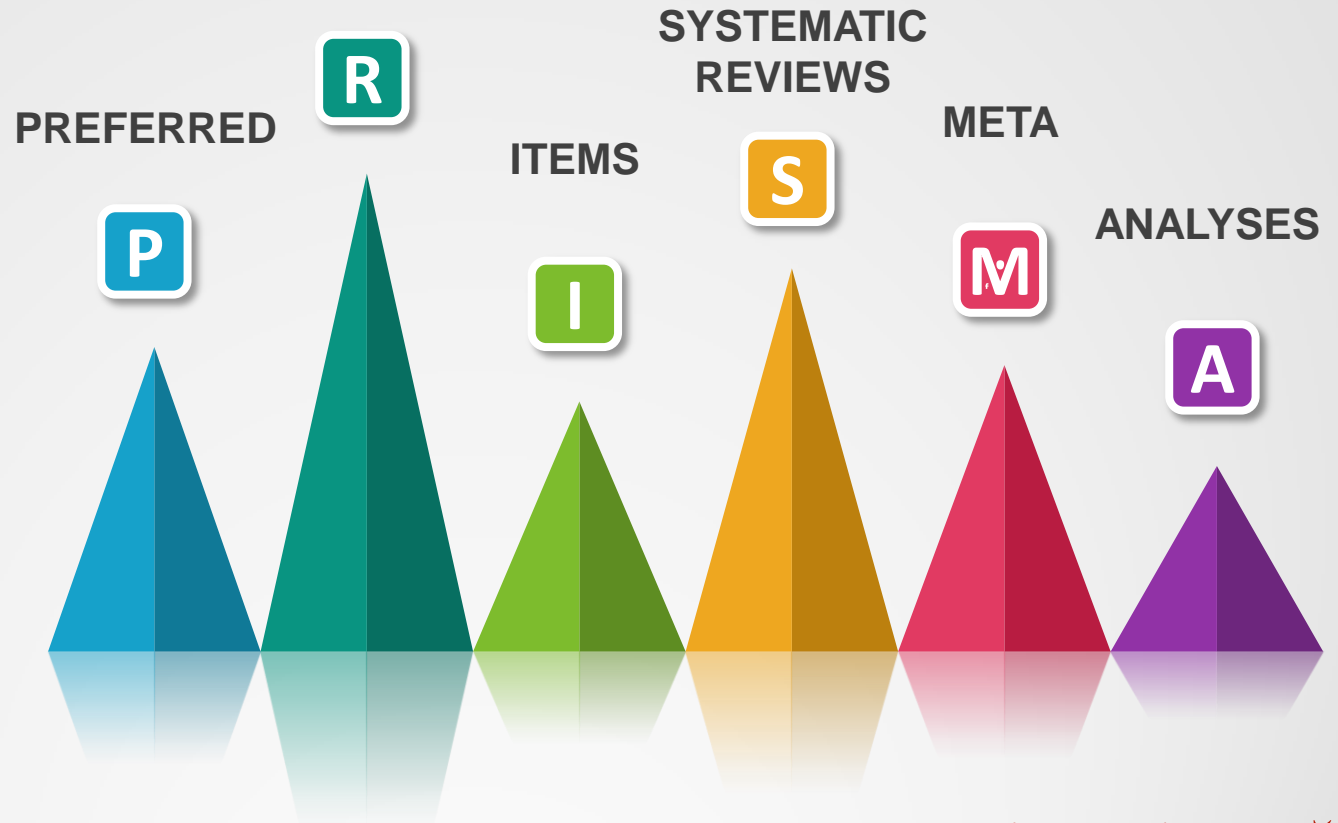
- Meta-analiz

- Lehte
- Aleyhte
- Güçlü
- Şartlı



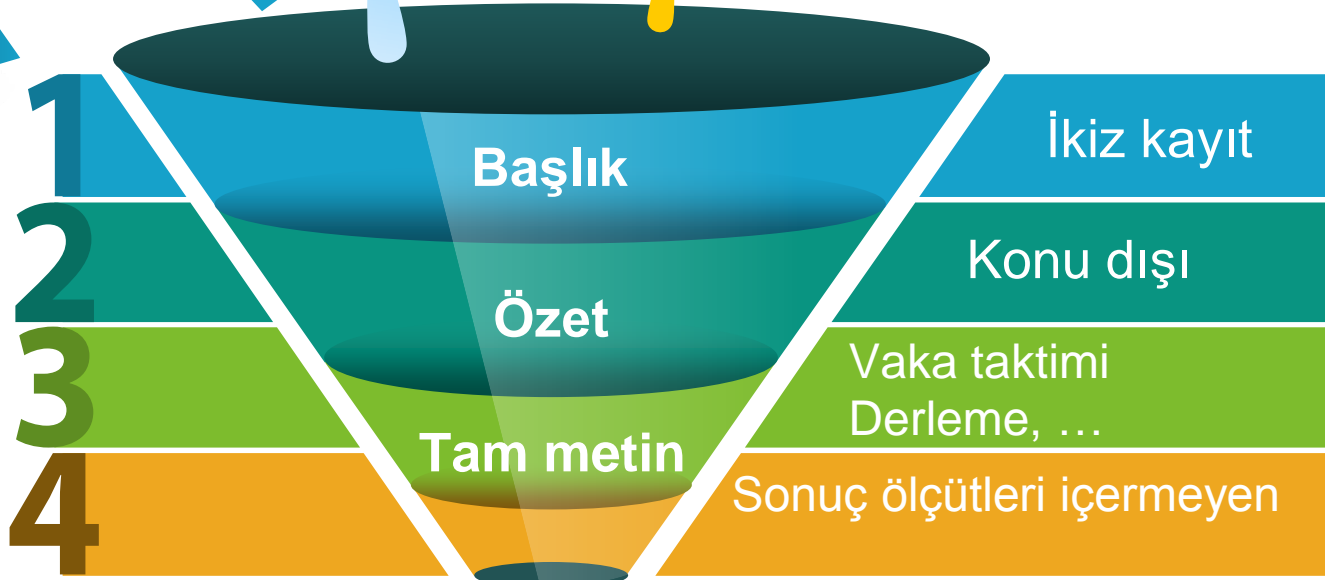
PRISMA

REPORTING



Veritabanları

Diğer



Yanılılık

Kesinlik – Geniş CI

Tutarlılık – Dağınık CI

Doğrudanlık

Mesut Mutluoğlu

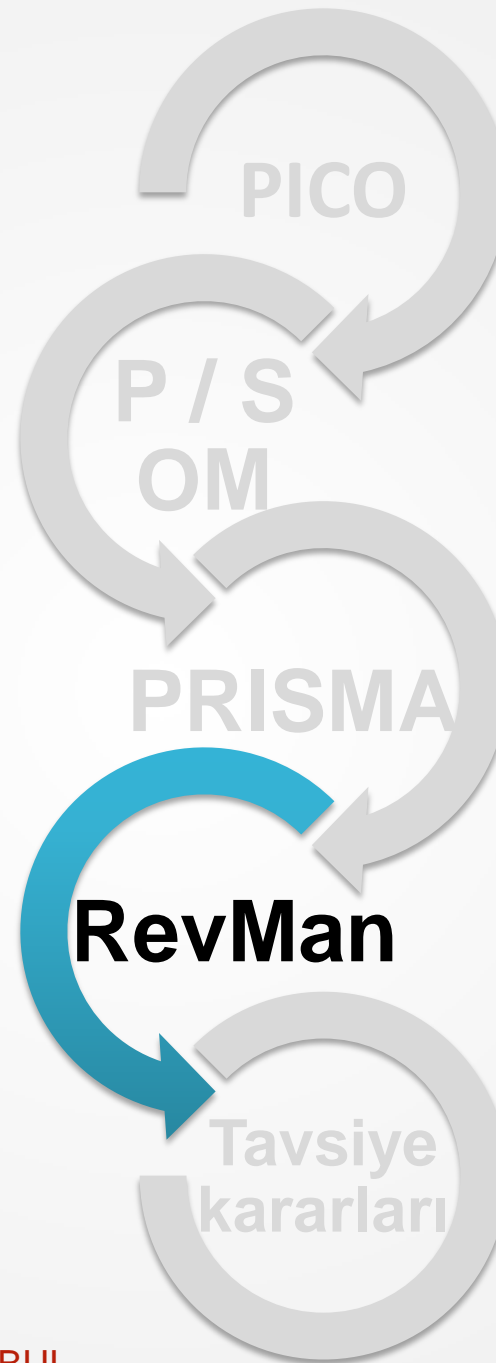
Table 9. Outcomes reported by study

| type | study | OUTCOME REPORTED | | | | | COMMENTS |
|------------------------------|--------------|------------------|---------------------------|------------------|----------------------|------------------------------|--|
| | | major amputation | incomplete healing (1 yr) | minor amputation | persistent infection | no change in quality of life | |
| RANDOMIZED CONTROLLED TRIALS | Doctor 1992 | | | | | | included |
| | Faglia 1996 | | | | | | included |
| | Lin 2001 | | | | | | excluded: abstract only without any outcomes of interest |
| | Abidia 2003 | | | | | | included: data on quality of life were not able to be included |
| | Kessler 2003 | | | | | | excluded: reported only for short-term outcomes (< 6 weeks) |
| | Duzgun 2008 | | | | | | included |
| | Löndahl 2010 | | | | | | included: data on quality of life were able to be included |
| | Kaur 2012 | | | | | | excluded: did not include populations of interest and did not include outcomes of interest |
| | Ma 2013 | | | | | | excluded: did not include outcomes of interest |

Table 9. Outcomes reported by study

| | | | | | | | |
|----------------------|-----------------|--|--|--|--|--|---|
| OBSERVATIONAL TRIALS | Hart 1979 | | | | | | excluded: did not include outcomes of interest |
| | Davis 1987 | | | | | | excluded: did not include outcomes of interest |
| | Baroni 1987 | | | | | | included: these studies may have had overlapping patients, so the last dataset for 1990 was used for analysis |
| | Oriani 1990 | | | | | | |
| | Oriani 1992 | | | | | | excluded: did not include non-HBO ₂ comparison grp |
| | Wattel 1991 | | | | | | excluded: did not include non-HBO ₂ comparison grp |
| | Cianci 1994 | | | | | | excluded: did not include any outcomes of interest |
| | Zamboni 1997 | | | | | | included |
| | Faglia 1998 | | | | | | excluded: did not include non-HBO ₂ comparison grp |
| | Kalani 2001 | | | | | | included |
| | Grollman 2001 | | | | | | excluded: did not include any outcomes of interest |
| | Fife 2002 | | | | | | excluded: did not include non-HBO ₂ comparison grp |
| | Strauss 2002 | | | | | | excluded: did not include non-HBO ₂ comparison grp |
| | Niinikoski 2003 | | | | | | excluded: did not include any outcomes of interest |
| | Fife 2007 | | | | | | excluded: did not include any outcomes of interest |
| | Oubre 2007 | | | | | | excluded: did not include non-HBO ₂ comparison grp |
| | Ong 2008 | | | | | | excluded: did not include non-HBO ₂ comparison grp |
| | Lyon 2008 | | | | | | excluded: did not include any outcomes of interest |
| | Kaya 2009 | | | | | | excluded: did not include non-HBO ₂ comparison grp |
| | Chen 2010 | | | | | | excluded: did not include any outcomes of interest |
| | Margolis 2013 | | | | | | included |
| | Tongson 2013 | | | | | | excluded: did not include any outcomes of interest |
| | Bishop 2013 | | | | | | excluded: did not include non-HBO ₂ comparison grp |

GRADE



- Patient
- Intervention
- Comparison
- Outcome

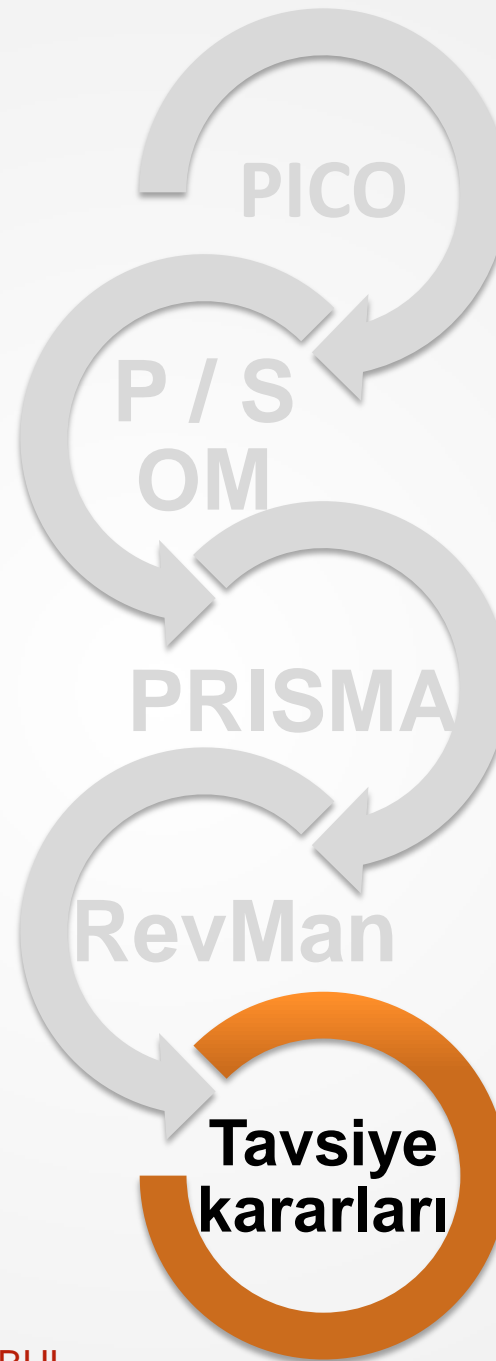
- Birincil sonuç ölçütleri
- İkincil sonuç ölçütleri

- Literatür taraması

- Meta-analiz

- Lehte
- Aleyhte
- Güçlü
- Şartlı

GRADE



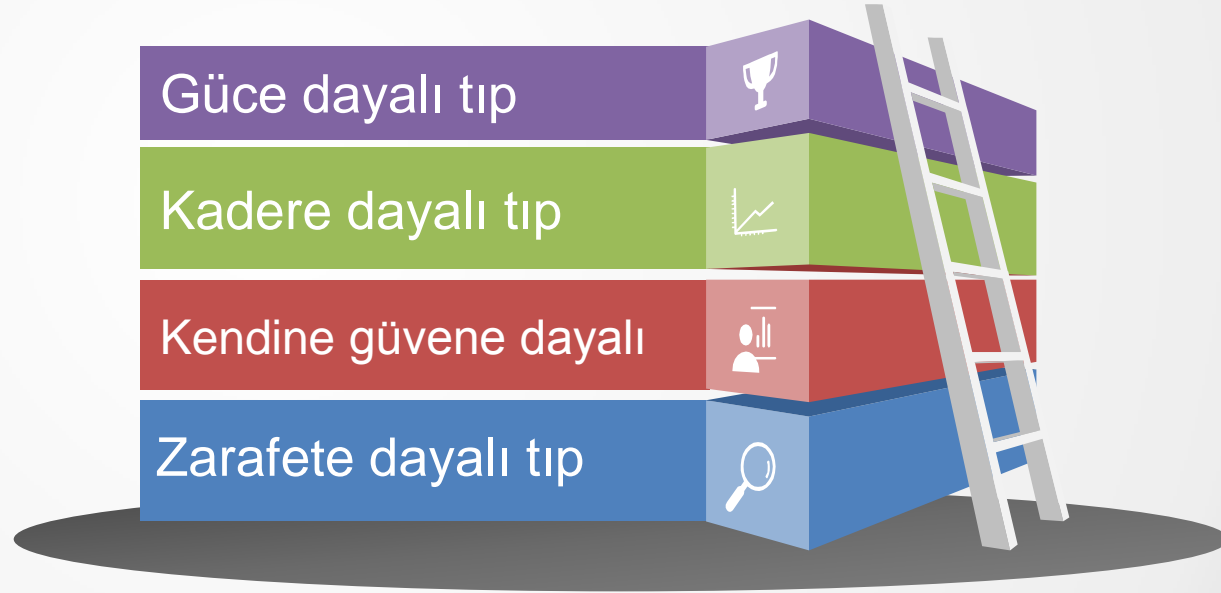
- Patient
- Intervention
- Comparison
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- Birincil sonuç ölçütleri
- İkincil sonuç ölçütleri

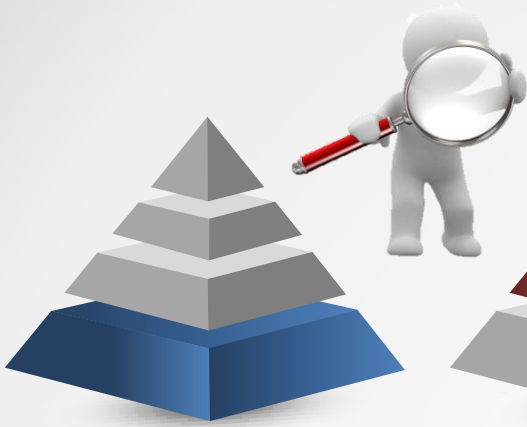
- Literatür taraması

- Meta-analiz

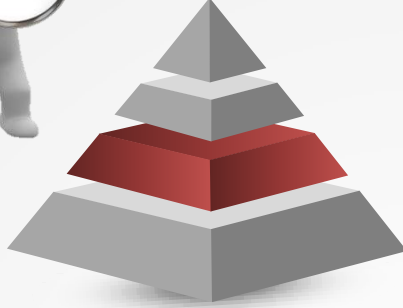
- Leyhte
- Aleyhte
- Güçlü
- Şartlı



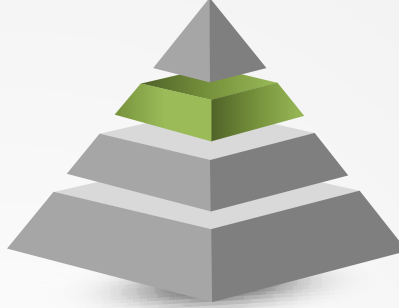




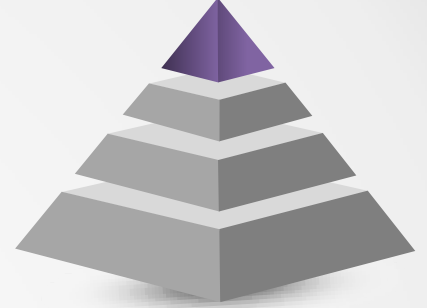
Çok düşük



Düşük



Orta



Yüksek

Zayıf



Anlaşmanın
sağlanamadığı
durumlar.

Nötr



Yeni çalışmaların
öneriyi değiştirme
olasılığı yüksek.

Şartlı



Yeni çalışmaların
öneriyi değiştirme
olasılığı var.

Güçlü



Yeni çalışmaların
öneriyi değiştirme
olasılığı düşük.

Tavsiye kararları



- **Wagner 1-2**

(Çok düşük seviyeli kanıt, şartlı öneri).



- **Wagner 3-5**
- **30 günlük standart tedavi ile belirgin fayda YOK**

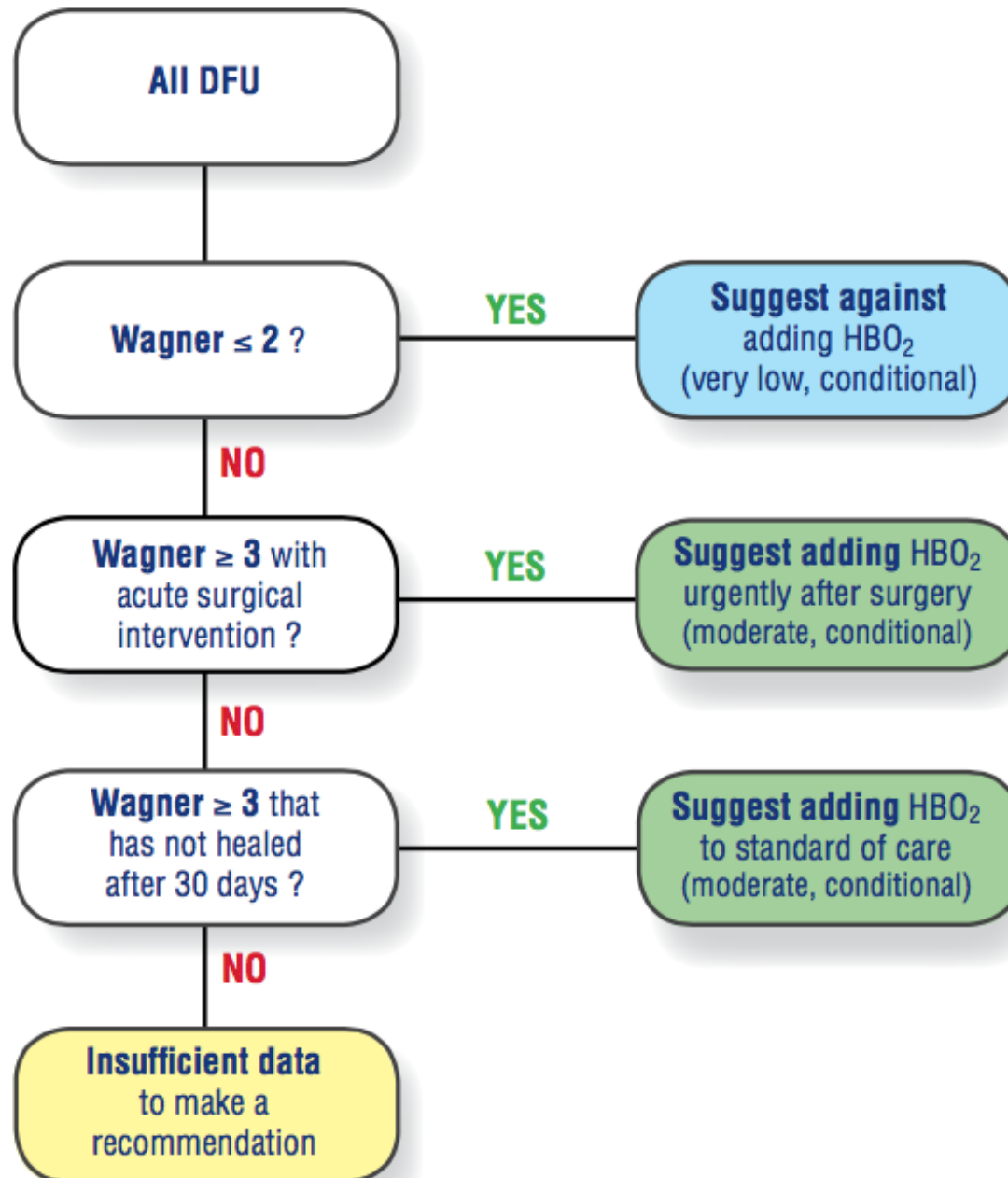
(orta-düzeyde kanıt, şartlı öneri).



- **Wagner 3-5**
- **Cerrahi debritleme geçiren**

(orta-düzeyde kanıt, şartlı öneri).

Figure 6. Algorithm for the use of HBO₂



IDSA

2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections^a

Benjamin A. Lipsky,¹ Anthony R. Berendt,² Paul B. Cornia,³ James C. Pile,⁴ Edgar J. G. Peters,⁵ David G. Armstrong,⁶ H. Gunner Deery,⁷ John M. Embil,⁸ Warren S. Joseph,⁹ Adolf W. Karchmer,¹⁰ Michael S. Pinzur,¹¹ and Eric Senneville¹²

¹Department of Medicine, University of Washington, Veterans Affairs Puget Sound Health Care System, Seattle; ²Bone Infection Unit, Nuffield Orthopaedic Centre, Oxford University Hospitals NHS Trust, Oxford; ³Department of Medicine, University of Washington, Veteran Affairs Puget Sound Health Care System, Seattle; ⁴Divisions of Hospital Medicine and Infectious Diseases, MetroHealth Medical Center, Cleveland, Ohio; ⁵Department of Internal Medicine, VU University Medical Center, Amsterdam, The Netherlands; ⁶Southern Arizona Limb Salvage Alliance, Department of Surgery, University of Arizona, Tucson; ⁷Northern Michigan Infectious Diseases, Petoskey; ⁸Department of Medicine, University of Manitoba, Winnipeg, Canada; ⁹Division of Podiatric Surgery, Department of Surgery, Roxborough Memorial Hospital, Philadelphia, Pennsylvania; ¹⁰Department of Medicine, Division of Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts; ¹¹Department of Orthopaedic Surgery and Rehabilitation, Loyola University Medical Center, Maywood, Illinois; and ¹²Department of Infectious Diseases, Dron Hospital, Tourcoing, France



8. Diyabetik ayak osteomiyelitinin tanı ve tedavisi nasıl olmalıdır ?

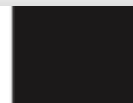


37. For specifically treating DFO, **we do not** currently support using adjunctive treatments such as **hyperbaric oxygen therapy**, growth factors (including granulocyte colony- stimulating factor), maggots (larvae), or topical negative pressure therapy (eg, vacuum-assisted closure) **(weak, low).**

10. Diyabetik ayak yaralarında hangi tedavi yöntemleri ve yara bakım ürünleri kullanılabilir ?



44. No adjunctive therapy has been proven to improve resolution of **infection**, but for **selected diabetic foot wounds** that are slow to heal, clinicians **might consider** using bioengineered skin equivalents (weak, moderate), growth factors (weak, moderate), granulocyte colony-stimulating factors (weak, moderate), **hyperbaric oxygen therapy (strong, moderate)**, or negative pressure wound therapy (weak, low).



IWGDF guidance on the diagnosis and management of foot infections in persons with diabetes

25. We suggest **not** using **any** **adjunctive treatments** for DFI (weak; low).



Several randomized clinical trials evaluated HBOT for treating DFUs, and some have shown an increased likelihood or **faster rates of wound healing and fewer major amputations**. Most of these studies included Wagner 3 ulcers, which can include patients with osteomyelitis, but **none** presented any subanalyses of patients with **infected DFUs** or specifically reported on infection-related outcome measures. **To date, there are no data to support using HBOT to treat either soft tissue infection or osteomyelitis.**

KLİMİK

Diyabetik Ayak Yarası ve Enfeksiyonunun Tanısı, Tedavisi ve Önlenmesi: Ulusal Uzlaşı Raporu

*Diagnosis, Treatment and Prevention of Diabetic Foot Wounds and Infections:
Turkish Consensus Report*

Neşe Saltoğlu¹, Önder Kılıçoğlu², Selçuk Baktıroğlu³, Zeynep Oşar-Siva⁴, Şamil Aktaş^{3,5}, Muzaffer Altındaş⁶, Caner Arslan⁷, Turan Aslan¹, Selda Çelik⁸, Aynur Engin¹, Haluk Eraksoy¹, Önder Ergönül¹, Bülent Ertuğrul¹, Serdar Güler⁹, Ayten Kadanalı¹, Lutfiye Mülazımoğlu¹, Nermin Olgun⁸, Oral Öncül¹, Ali Öznur², İlhan Satman¹⁰, İrfan Şencan¹¹, Özlem Tanrıöver¹², Özge Turhan¹, Abdullah Kemal Tuygun⁷, Hasan Tüzün⁷, Ahmet Çınar Yastı¹³, Temel Yılmaz¹⁴



KLİMİK

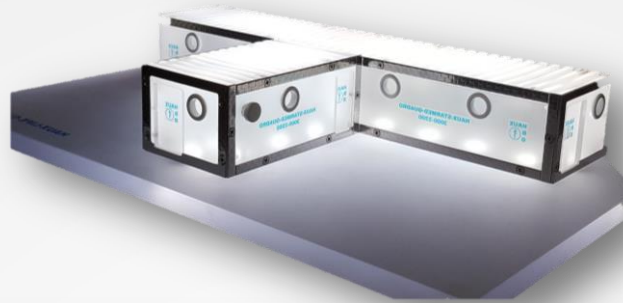
Soru 2: Diyabetik Ayak İnfeksiyonlarında Hiperbarik Oksijen Neden Kullanılır?



Bununla birlikte ülkemizde HBO olanakları, başka ülkelerdekilerle karşılaştırılamayacak kadar çok sayıda ve **yaygın** durumdadır. HBO tedavi **ücreti** bu raporun yayımlandığı tarih itibariyle seans başına 55 TL olup, Batı ülkelerinin neredeyse onda biri düzeyindedir ve **sosyal güvenlik sistemi** tarafından karşılanmaktadır.



ECHM



| CONDITION | ACCEPTED | | | NOT ACCEPTED | | |
|--|-------------------|---|---|-------------------|---|---|
| | Level of Evidence | | | Level of Evidence | | |
| | A | B | C | D | E | F |
| Type II | | | | | | |
| Diabetic Foot Lesion | | X | | | | |
| Compromised Skin Graft and Musculocutaneous Flap | | | X | | | |
| Osteoradionecrosis (other bones) | | | X | | | |
| Radio-induced Proctitis / Enteritis | | | X | | | |
| Radio-induced Lesions of Soft Tissues | | | X | | | |
| Surgery and Implant in Irradiated Tissue (preventive action) | | | X | | | |
| Sudden Deafness | | | X | | | |
| Ischemic Ulcer | | | X | | | |
| Refractory Chronic Osteomyelitis | | | X | | | |
| Neuroblastoma Stage IV | | | X | | | |





ORIGINAL ARTICLE

Is additional hyperbaric oxygen therapy cost-effective for treating ischemic diabetic ulcers? Study protocol for the Dutch DAMOCLES multicenter randomized clinical trial

Robert M STOOKENBROEK,^{1,†} Trientje B SANTEMA,^{1,†} Mark JW KOELEMAY,¹ Rob A van HULST,² Dink A LEGEMATE,¹ Jim A REEKERS³ and Dirk T UBBINK¹

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[†]These authors contributed equally to this work.

Trial registration: Dutch Clinical Trials
Register NTR3944

Received 21 February 2014; accepted 20
March 2014.

doi: 10.1111/1753-0407.12155

Abstract

Background: The value of hyperbaric oxygen therapy (HBOT) in the treatment of diabetic ulcers is still under debate. Available evidence suggests that HBOT may improve the healing of diabetic ulcers, but it comes from small trials with heterogeneous populations and interventions. The DAMOCLES-trial will assess the (cost-)effectiveness of HBOT for ischemic diabetic ulcers in addition to standard of care.

Methods: In a multicenter randomized clinical trial, including 30 hospitals and all 10 HBOT centers in the Netherlands, we plan to enroll 275 patients with Types 1 or 2 diabetes, a Wagner 2, 3 or 4 ulcer of the leg present for at least 4 weeks, and concomitant leg ischemia, defined as an ankle systolic blood pressure of <70 mmHg, a toe systolic blood pressure of <50 mmHg or a forefoot transcutaneous oxygen tension (T_{cpO₂}) of <40 mmHg. Eligible patients may be candidates for revascularization. Patients will be randomly assigned to standard care with or without 40 HBOT-sessions.

Results: Primary outcome measures are freedom from major amputation after 12 months and achievement of, and time to, complete wound healing. Secondary endpoints include freedom from minor amputations, ulcer recurrence, T_{cpO₂}, quality of life, and safety. In addition, we will assess the cost-effectiveness of HBOT for this indication.

Conclusion: The DAMOCLES trial will be the largest trial ever performed in the realm of HBOT for chronic ulcers, and it is unique for addressing patients with ischemic diabetic foot ulcers who may also receive vascular reconstructions. This matches the treatment dilemma in current clinical practice.

İyileşmeyen yara



➤ Debritman, abse / drenaj ?

➤ İskemi ?

➤ Yükten arındırma ?

➤ Metabolik denge ?

➤ Osteomiyelit ?

➤ Doğru yara örtüsü?

➤ Hasta uyumlu mu ?



Teşekkürler

<http://www.turk-day.org>

