**Supplementary Materials:** Demographic Gaps and Requirements for Participation: A Systematic Review of Clinical Trial Designs in Hidradenitis Suppurativa

JaBreia Fanita James, BS; Victoria M. Madray, MD; Nicole Salame, MD; Samar Babikir Hasan, MD;Mia Sohn White, MILS; Jason Richard Barron, MPH; Joslyn Kirby, MD MEd MS; John Robert Ingram, MD; Lauren Anne Vigil Orenstein, MD MScb

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**Supplemental Table 1. Characteristics of hidradenitis suppurativa randomized controlled trials**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **N** | **Study years** | **Location** | **Intervention** | **Control** | **Blinding** | **1̊ Outcome** | **Funding** |
| **Pioneer II[**1**]**  | 326 | 2011-2014 | Europe and USA | Adalimumab  | Placebo  | Double | HiSCR[2] | Industry |
| **Pioneer I**[1] | 307 | 2011-2014 | Europe and USA | Adalimumab  | Placebo | Double | HiSCR[2] | Industry |
| **Buimer**[3] | 200 | 2008c  | Netherlands | Excision and closure with gentamicin sponge | Excision and closure without sponge  | NR  | Postoperative complications | Investigator initiated  |
| **Kimball 2012**[4,5] | 154 | 2009-2010 | Europe and USA | Adalimumab | Placebo  | Double | HS-PGA[2,6] | Industry  |
| **Jemec**[7] | 46 | 1996-1997b | Denmark | Oral tetracycline + topical placebo | Topical clindamycin + oral placebo | Double | VAS | IndustryPartnership  |
| **Yildiz**[8] | 43 | 2012-2014 | Turkey  | Hyperbaric oxygen, oral clindamycin + rifampin | Oral clindamycin +rifampin | None | NR | NR |
| **Wilden**[9] | 43 | 2014-2015 | Germany  | IPL+RF (LAight®) | RF or IPL | Doublea | Number of inflammatory nodules, abscesses, and draining fistulae | Industry Partnership  |
| **Grant**[10] | 38 | 2005-2008 | USA | Infliximab | Placebo  | Double | HSSI[4,11] | Investigator Initiated  |
| **Naouri[**12] | 36 | 2021c | France  | Nd:YAG laser (1064 nm) | No treatment on contralateral side  | Single  | Number of inflammatory lesions  | Investigator Initiated  |
| **Fajgenbaum**[13] | 32 | 2016-2017 | USA | Intralesional triamcinolone | Saline injection  | Double | Days to resolution of lesions, pain reduction | Investigator Initiated  |
| **Angel[**14] | 31 | 1987c  | NR | Staphage lysate | Placebo  | Double | Decrease in "point system" used to grade severity | Investigator initiated |
| **Mortimer**[15] | 24 | 1986c | United Kingdom  | Ethinyloestradiol + cyproterone acetate | Ethinyloestradiol + norgestrel | Double | NR | Industry Partnership  |
| **Andersen[**16] | 24d | 2017-2018 | Denmark | IPL (Palomar LuxY, Series II, Cynosure Inc) | No treatment on contralateral side  | Single | HiSCR[2] | Investigator Initiated  |
| **Mahmoud**[17.18] | 22 | 2007-2009 | USA  | Nd:YAG laser (1064 nm) + Topical clindamycin and BPO | Topical clindamycin and BPO | Single  | HS-LASI[17] | Investigator initiated  |
| **Miller**[19] | 21 | 2007-2010 | Denmark  | Adalimumab | Placebo  | Double | Sartorius[11]and Hurley scoring systems | Industry Partnership |
| **Adams[**20] | 20 | 2010c | USA | Etanercept | Placebo | Double | 4-point PGA | Industry Partnership |
| **Tzanetakou[**21] | 20e | 2012-2014 | Greece  | Anakinra | Placebo  | Double | HS disease severity[22] | Investigator Initiated |
| **Kanni[**23] | 20 | 2015-2017 | Greece  | MABp1 | Placebo  | Double | HiSCR[2] | Industry Partnership  |
| **Vossen**[24] | 20 | 2017 | Netherlands | Apremilast  | Placebo  | Double | HiSCR[2] | Industry  |
| **Grimstad**[25] | 20 | 2017-2018 | Norway | BTX-B (NeuroBlock®) | Placebo | Double  | DLQI[26] | Investigator Initiated |
| **Azim[**27] | 20 | 2017 | Egypt | Fractional CO2 (10,600nm) + Nd:YAG (1064 nm) | Nd:YAG (1064 nm) | Single | HS-PGA[2,6] | NR |
| **Highton[**28] | 18 | 2011c  | United Kingdom | Intense pulsed light (Harmony®) | No treatment on contralateral axilla | Single  | Sartorius score[11] | NR  |
| **Fadel**[29] | 11 | 2013 | Egypt  | IPL (EPI-C Plus ®) + niosomal MB gel | IPL + free MB gel | Single | HS-LASI[17]  | Investigator Initiated  |

Supplemental Table 1 Key:

BPO: Benzoyl peroxide; BTX: Botulinum Toxin; CRP: C-reactive Protein; DLQI[26]: Dermatology Life Quality Index; ESR: Erythrocyte Sedimentation Rate

HiSCR[2]: Hidradenitis Suppurativa Clinical Response; HS-LASI[17]: Hidradenitis Suppurativa Lesion, Area and Severity Index; HS-PGA[2,6]: Hidradenitis Suppurativa Physician's Global Assessment; HSSI[4,30]: HS Severity Index; IPL: Intense pulsed light; MB: methylene blue; N: number of participants randomized

NR: Not reported; RF: Radiofrequency; US: United States; VAS: Visual Analogue Scale

aOnly patients in the IPL+RF and IPL only groups were blinded.

bFrom private communication with authors.

cPublication date listed, as study dates not reported.

d17 of the 24 randomized participants were included in the final analysis

e 19 of the 20 randomized participants were included in the final analysis

**Supplemental Table 2: Other patients groups excluded due to medical co-morbidities**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study** | **CHF** | **HIV** | **History of Malignancy** |
| **Pioneer II[**1**]**  | **✕** | **✕** | **✕** |
| **Pioneer I**[1] | **✕** | **✕** | **✕** |
| **Buimer**[3] | **✓**  | **✓**  | **✓**  |
| **Kimball 2012**[4,5] | **✕** | **✕** | **✕** |
| **Jemec**[7] |  **✕**a, b | **✓**  | **✓**  |
| **Yildiz**[8] |  **✕**a | **✓**  | **✓**  |
| **Wilden**[9] | **✓**  | **✓**  | **✓**  |
| **Grant**[10] | **✕** | **✕** | **✕** |
| **Naouri[**12] | **✓**  | **✓**  | **✓**  |
| **Fajgenbaum**[13] | **✓**  | **✓**  | **✓**  |
| **Angel[**14] | **✓**  | **✓**  | **✓**  |
| **Mortimer**[15] | **✓**  | **✓**  | **✓**  |
| **Andersen[**16] | **✓**  | **✓**  | **✓**  |
| **Mahmoud**[17.18] | **✓**  | **✓**  | **✓**  |
| **Miller**[19] | **✕**b | **✕**b | **✕**b |
| **Adams[**20] | **✕** | **✕** | **✕** |
| **Tzanetakou[**21] | **✓** | **✕** | **✕** |
| **Kanni[**23] | **✓** | **✕** | **✓** |
| **Vossen**[24] | **✕**a | **✕**a | **✕**a |
| **Grimstad**[25] | **✓**  | **✓**  | **✓**  |
| **Azim[**27] | **✕**a | **✕**a | **✕**a |
| **Highton[**28] | **✓**  | **✓**  | **✓**  |
| **Fadel**[29] | **✓**  | **✓**  | **✓**  |
| **Studies with exclusion, n (%)** | **10 (43)** | **10 (43)** | **9 (39)** |

Supplemental Table 2 Key:

HIV: Human Immunodeficiency Virus; CHF: Congestive heart failure

**✓** Included; **✕**Excluded;

aIntervention unlikely to cause harm to this subset of patients based on medical comorbidities

bObtained through personal correspondence with authors

**Supplemental Figure 1: Summary of literature search and study selection**



**Appendix 1: Literature Search Strategies:**

**PubMed (pubmed.gov)**

1. "hidradenitis suppurativa"[MeSH Terms] OR "hidradenitis suppurativa"[TW] OR acne inversa[TW]
2. "Clinical Trial" [Publication Type] OR "Clinical Trials as Topic"[Mesh] OR “clinical trial\*”[TW] OR “controlled clinical trial\*”[TW] OR “randomized clinical trial\*”[TW]
3. #1 AND #2
4. #3 AND English [lang]

**EMBASE (embase.com)**

1. 'suppurative hidradenitis'/exp OR 'hidradentitis supprativa':ti,ab OR 'acne inversa':ti,ab 'clinical trial'/exp OR 'clinical trial\*':ti,ab OR (clinical NEAR/2 trial\*) OR (controlled NEAR/2 ‘clinical trial\*’) OR (randomized NEAR/2 ‘clinical trial\*’)
2. #1 AND #2
3. #3 AND [english]/lim AND ('article'/it OR 'article in press'/it OR 'review'/it)

**Central (cochranelibrary.com)**

1. MeSH descriptor: [Hidradenitis Suppurativa] explode all trees
2. “hidradenitis suppurativa”:ti,ab
3. "acne inversa":ti,ab
4. #1 OR #2 OR #3
5. MeSH descriptor: [Clinical Trial] explode all trees
6. "clinical trial":ti,ab OR clinical NEAR/2 trial\* OR (controlled NEAR/2 “clinical trial\*”) OR (randomized NEAR/2 “clinical trial\*”)
7. #5 OR #6
8. #4 AND #7

 **Science Citation Index Expanded**

**Social Sciences Citation Index**

**Arts & Humanities Citation Index**

**Conference Proceedings Citation Index – Science**

**Conference Proceedings Citation Index – Social Science & Humanities**

**Book Citation Index – Science**

**Book Citation Index – Social Sciences & Humanities**

**Emerging Sources Citation Index**

**Current Chemical Reactions**

1. (TS=("hidradenitis suppurativa") OR TS=("acne inversa"))
2. (TS=(clinical NEAR/2 trial\*) OR TS=(controlled NEAR/2 “clinical trial\*”) OR TS=(randomized NEAR/2 “clinical trial\*”))
3. #1 AND #2
4. #3 AND LANGUAGE: (English) AND (Article OR Review)

**Supplemental Reference**

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