

Efficacy and safety of second-line agents for treatment of metastatic castration-resistant prostate cancer progressing after docetaxel. A systematic review and meta-analysis

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SEARCH STRATEGIES FOR INTERNATIONAL BIBLIOGRAPHICAL DATABASES OF MEDICINE AND LIFE SCIENCES

1. MEDLINE search strategy (includes MEDLINE in-Process database [OVIDSP])

1. exp Prostatic Neoplasms/
2. (prostat* adj3 (cancer* or carcinoma* or malignan* or tumo?r* or neoplas* or adeno*)).tw.
3. 1 or 2
4. Taxoids/
5. (docetax* or taxoter* or d?xotel or RP 56976 or NSC 628503 or docefrez or TXT).tw.
6. 15H5577CQD.m.
7. 4 or 5 or 6
8. randomized controlled trial.pt.
9. controlled clinical trial.pt.
10. randomized.ab.
11. placebo.ab.
12. drug therapy.fs.
13. randomly.ab.
14. trial.ab.
15. groups.ab.
16. or/8-15
17. exp animals/ not humans.sh.
18. 16 not 17
19. 3 and 7 and 18
20. limit 19 to yr="2004-Current"

2. EMBASE search strategy [OVIDSP]

1. exp prostate tumor/
2. (prostat* adj3 (cancer* or carcinoma* or malignan* or tumo?r* or neoplas* or adeno*)).tw.
3. 1 or 2

4. exp docetaxel/
5. (docetax* or taxoter* or d?xotel or RP 56976 or NSC 628503 or docefrez or TXT).tw.
6. 114977-28-5.m.
7. or/4-6
8. crossover procedure/
9. double-blind procedure/
10. randomized controlled trial/
11. single-blind procedure/
12. (random* or factorial* or crossover* or cross over* or placebo* or assign* or allocat* or volunteer*).mp.
13. ((doubl* or singl*) adj blind*).mp.
14. or/8-13
15. 3 and 7 and 14
16. limit 15 to yr="2004-Current"

3. PubMed search strategy

- #19 Search (#3 and #7 and #18)
#18 Search (#16 NOT #17)
#17 Search (animals[MeSH Terms]) NOT humans[MeSH Terms]
#16 Search (#8 or #9 or #10 or #11 or #12 or #13 or #14 or #15)
#15 Search groups[Title/Abstract]
#14 Search trial[Title/Abstract]
#13 Search randomly[Title/Abstract]
#12 Search drug therapy[MeSH Subheading]
#11 Search placebo[Title/Abstract]
#10 Search randomized[Title/Abstract]
#9 Search controlled clinical trial[Publication Type]
#8 Search randomized controlled trial[Publication Type]

- #7 Search (#4 or #5 or #6)
- #6 Search ("RP 56976" or "NSC 628503"[All Fields])
- #5 Search (docetax* or taxoter* or d?xotel or docefrez or TXT[Title/Abstract])
- #4 Search taxoids[MeSH Terms]
- #3 Search (#1 or #2)
- #2 Search (prostat*[Title/Abstract]) AND (cancer* or carcinoma* or malignon* or tumor* or tumour* or neoplas* or adeno*[Title/Abstract])
- #1 Search prostatic neoplasms[MeSH Terms]

4. The Cochrane Library search strategy

- #1 MeSH descriptor: [Prostatic Neoplasms] explode all trees
- #2 (prostat* near/3 (cancer* or carcinoma* or malignan* or tumor*r* or neoplas* or adeno*)):ti,kw,ab
- #3 #1 or #2
- #4 MeSH descriptor: [Taxoids] explode all trees
- #5 (docetax* or taxoter* or d?xotel or RP 56976 or NSC 628503 or docefrez or TXT):ti,kw,ab
- #6 15H5577CQD
- #7 114977-28-5
- #8 #4 or #5 or #6 or #7
- #9 #3 and #8

5. Web of Science Core Collection and Conference Proceedings Citation Index - Science (CPCI-S) search strategy

- #19 #18 AND #13 AND #12
- #18 #17 OR #16 OR #15 OR #14
- #17 TS=15H5577CQD
- #16 TS="NSC 628503"
- #15 TS="rp 56976"
- #14 TS=(docetax* or taxoter* or d?xotel or docefrez or TXT)
- #13 TS=((prostat* NEAR/3 (cancer* or carcinoma* or malignan* or tumor*r* or neoplas* or adeno*)))
- #12 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
- #11 TS=double blind*
- #10 TS=single blind*
- #9 TS=placebo*
- #8 TS=random*
- #7 TS=prospective stud*
- #6 TS=follow up stud*
- #5 TS=controlled trial*
- #4 TS=evaluation stud*
- #3 TS=comparative stud*
- #2 TS=research design*
- #1 TS=clinical trial*

6. Biosis search strategy

- #19 #18 AND #13 AND #12
- #18 #17 OR #16 OR #15 OR #14
- #17 TS=15H5577CQD
- #16 TS="NSC 628503"
- #15 TS="rp 56976"
- #14 TS=(docetax* or taxoter* or d?xotel or docefrez or TXT)

- #13 TS=((prostat* NEAR/3 (cancer* or carcinoma* or malignan* or tumor*r* or neoplas* or adeno*)))
- #12 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11
- #11 TS=double blind*
- #10 TS=single blind*
- #9 TS=placebo*
- #8 TS=random*
- #7 TS=prospective stud*
- #6 TS=follow up stud*
- #5 TS=controlled trial*
- #4 TS=evaluation stud*
- #3 TS=comparative stud*
- #2 TS=research design*
- #1 TS=clinical trial*

7. LILACS search strategy

((prostat\$) and (cancer\$ or carcinoma\$ or neoplas\$ or adenocarcinoma\$ or tumor\$ or tumours\$) and (doxetax\$ OR taxoter\$ OR d?xotel or "RP 56976" OR "NSC 628503" OR docefrez OR TXT)) AND ((PT:"randomized controlled trial" OR PT:"controlled clinical trial" OR PT:"multicenter study" OR MH:"randomized controlled trials as topic" OR MH:"controlled clinical trials as topic" OR MH:"multicenter study as topic" OR MH:"random allocation" OR MH:"double-blind method" OR MH:"single-blind method") OR ((ensaio\$ OR ensayo\$ OR trial\$) AND (azar OR acaso OR placebo OR control\$ OR aleat\$ OR random\$ OR enmascarado\$ OR simpleciego OR ((simple\$ OR single OR duplo\$ OR doble\$ OR double\$) AND (cego OR ciego OR blind OR mask))) AND clinic\$)) AND NOT (MH:animals OR MH:rabbits OR MH:rats OR MH:primates OR MH:dogs OR MH:cats OR MH:swine OR PT:"in vitro")

OTHER SOURCES OF INFORMATION

1. On-line clinical trial registers

The WHO International Clinical Trials Registry Platform (ICTRP) (<http://apps.who.int/trialsearch/>), the meta-register of 'Current Controlled Trials' (<http://www.controlled-trials.com/>) and the US registry of clinical trials (<http://www.clinicaltrials.gov/>) were searched for data concerning ongoing, completed or terminated clinical trials on mCRPC.

Searches were performed by entering the keywords "prostate cancer AND docetaxel".

2. Clinical trial protocols

The protocols and additional data of included studies were retrieved as on-line supplementary material from journal web pages or clinical trial registers.

- The AFFIRM study protocol was retrieved from: www.nejm.org/doi/suppl/10.1056/NEJMoa1207506/suppl_file/nejmoa1207506_protocol.pdf
- The CA184-043 study protocol was retrieved from:

www.clinicaltrialsregister.eu/ctr-search/trial/2008-003314-97/GB/

- The Cou-AA-301 study protocol was retrieved from: www.nejm.org/doi/suppl/10.1056/NEJMoa1014618/suppl_file/nejmoa1014618_protocol.pdf
- The TAK-700 study protocol was retrieved from: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2011-002965-39/GB>
- The TROPIC study protocol was not available.
- The TROPIC study FDA Medical Review was retrieved from: www.accessdata.fda.gov/drugsatfda_docs/nda/2010/201023s000MedR.pdf
- The COU-AA-301 study FDA Medical Review was retrieved from: www.accessdata.fda.gov/drugsatfda_docs/nda/2011/202379Orig1s000MedR.pdf
- The AFFIRM study FDA Medical Review was retrieved from: www.accessdata.fda.gov/drugsatfda_docs/nda/2012/203415Orig1s000MedR.pdf

3. Handsearching

Handsearching was performed on the web pages containing the abstracts of all scientific contributions presented at international meetings of the European Association of Urology (<http://www.uroweb.org/>) and of the American Urological Association (<http://www.auanet.org/>). Search was performed by entering the keyword "prostate cancer" in these abstract databases.

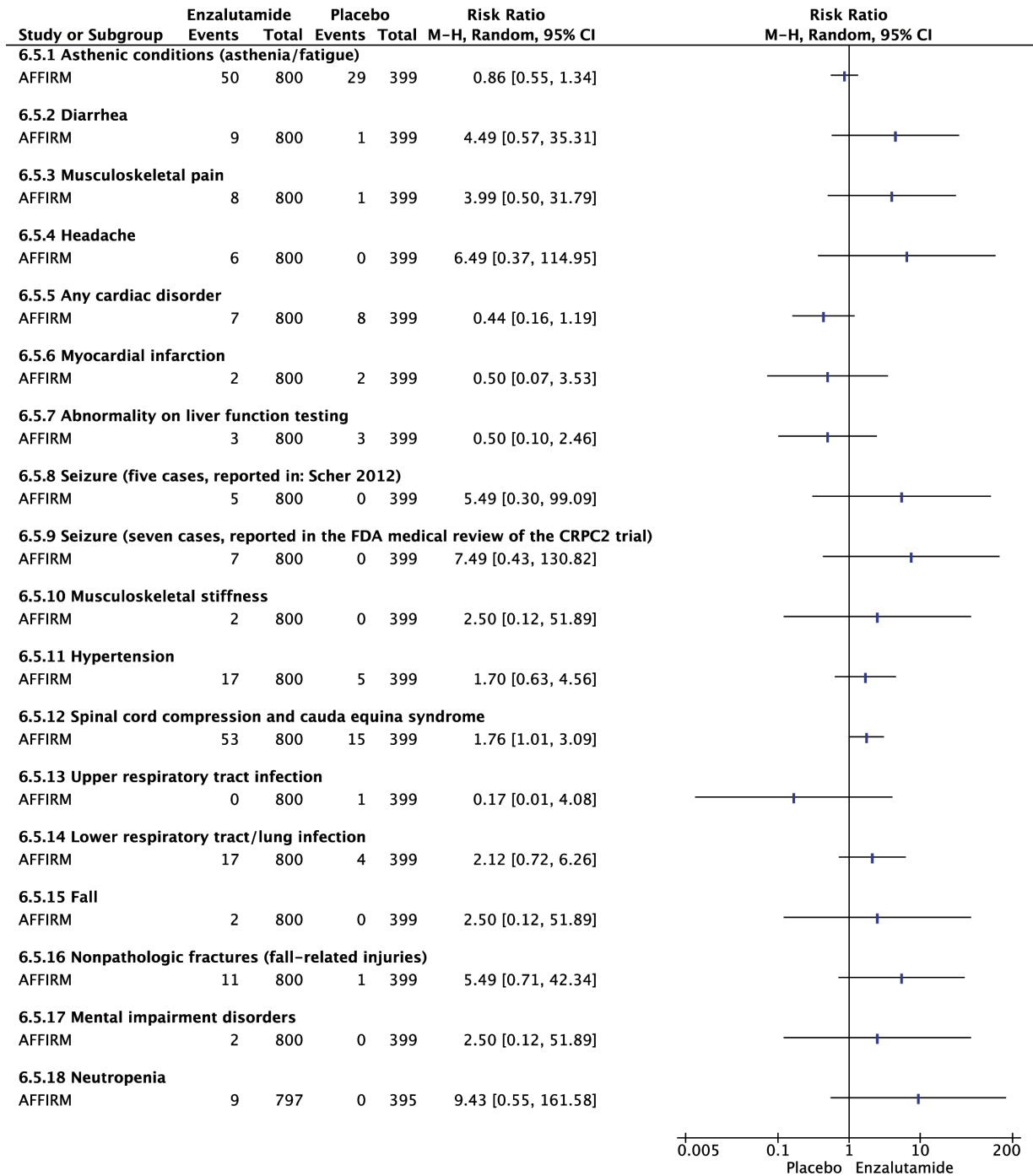
4. Medicine agencies reports and medical reviews

Food and Drug Administration (FDA) medical reviews of included studies, and other publicly available reports and reviews from international and national drug/medicine agencies concerning the trials included in the present review were retrieved from the world-wide web by performing open research using common search engines (e.g., <http://www.google.com>).

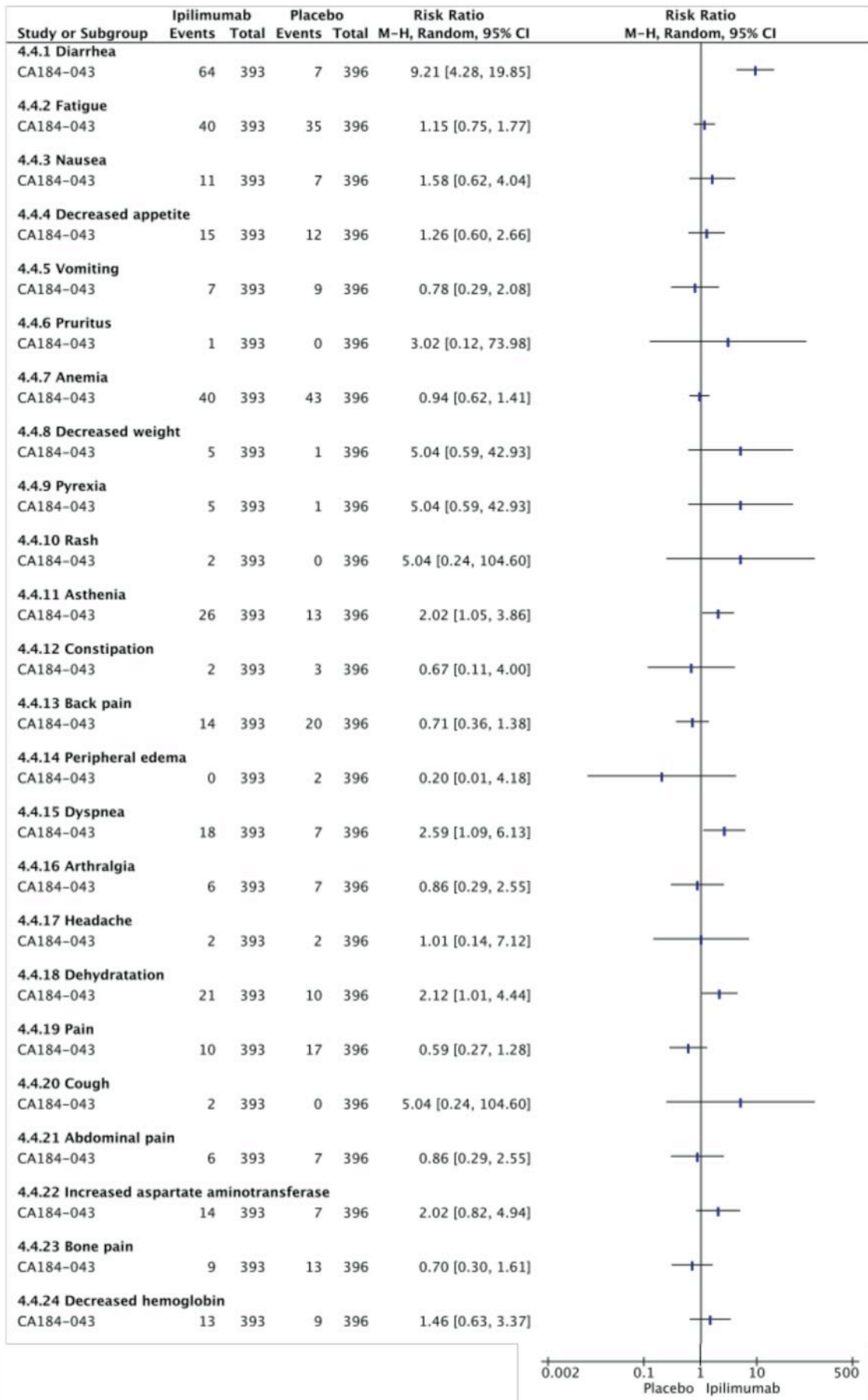
- A NICE Evidence Review Group report of the TROPIC study, issued by the Health Technology Assessment Program of the National Institute for Health Research, edited by the School of Health and Related Research (ScHARR-TAG), University of Sheffield, UK, was retrieved on-line (<http://www.nice.org.uk/guidance/ta255/documents/prostate-cancer-cabazitaxel-evidence-review-group-report3>), and was used for the review process.
- A Warwick Evidence report on the COU-AA-301 study (Health Technology Assessment Program of the National Institute for Health Research, UK National Health Service) was retrieved on-line (<https://www.nice.org.uk/guidance/ta259/documents/prostate-cancer-metastatic-castration-resistant-abiraterone-following-cytotoxic-therapy-evidence-review-group-report2>) and was used for the review process.

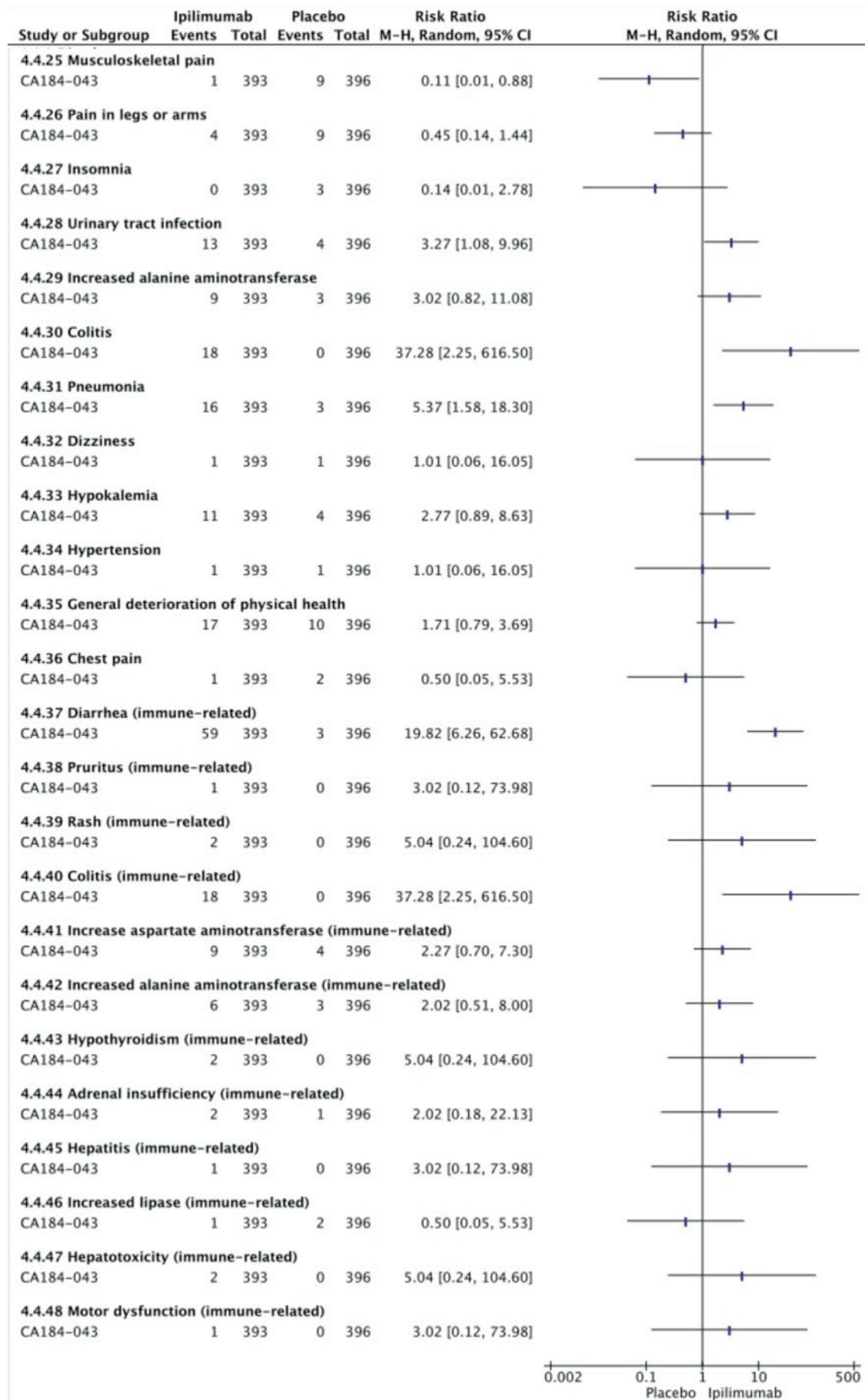
SEVERE ADVERSE EFFECTS OF TREATMENT (GRADE 3 OR HIGHER)

1. AFFIRM study (enzalutamide versus placebo)



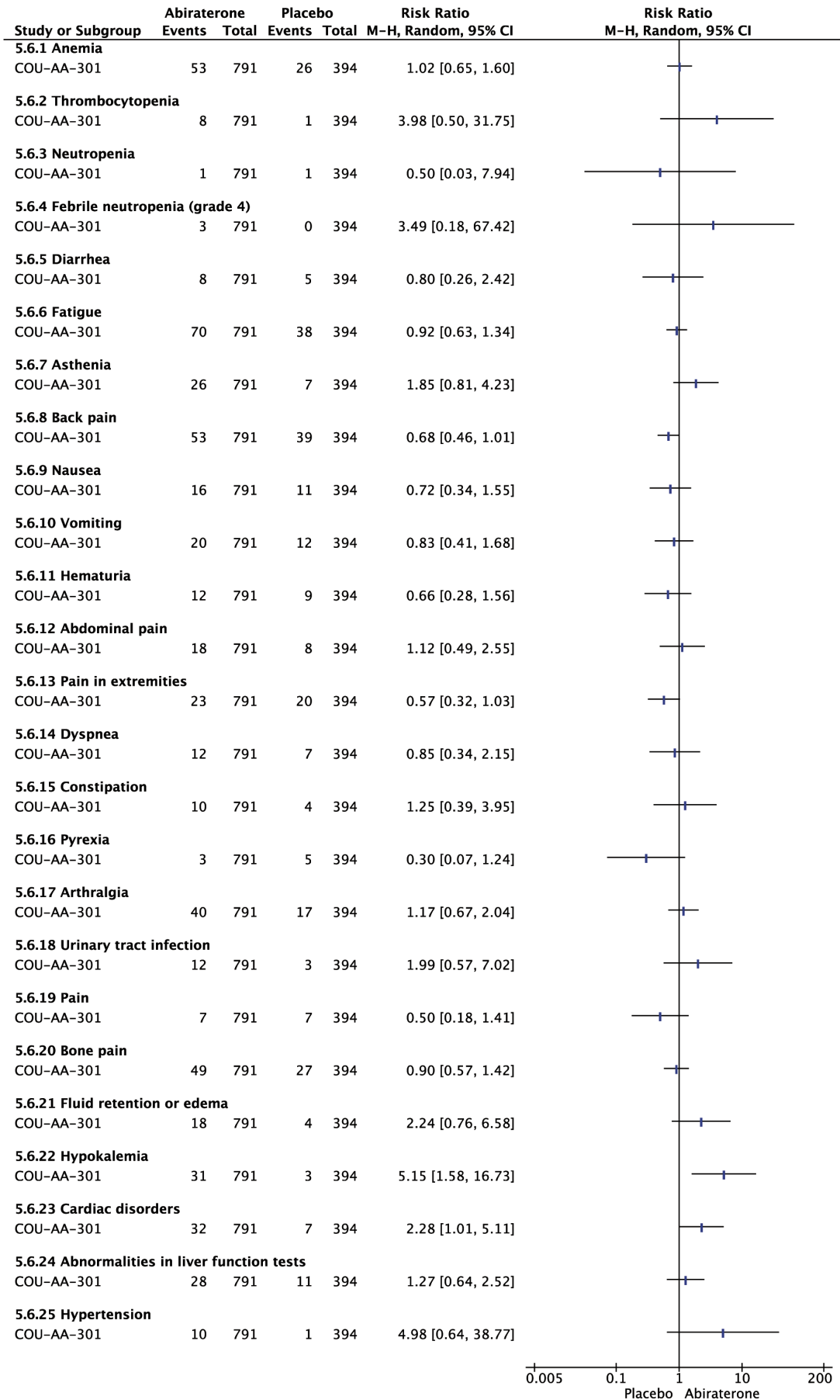
2. CA184-043 study
(ipilimumab versus placebo)



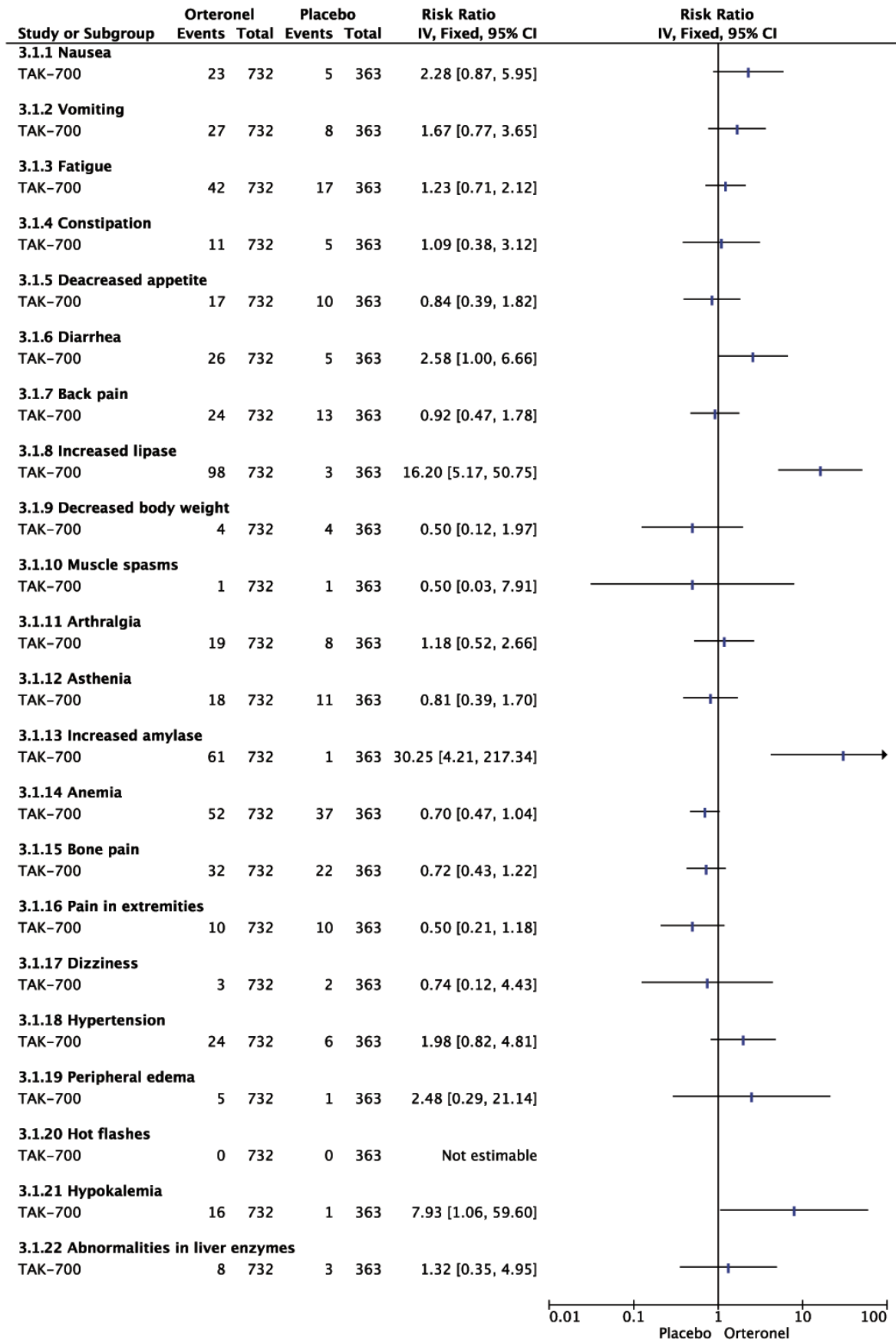


2. CA184-043 study (continuation)

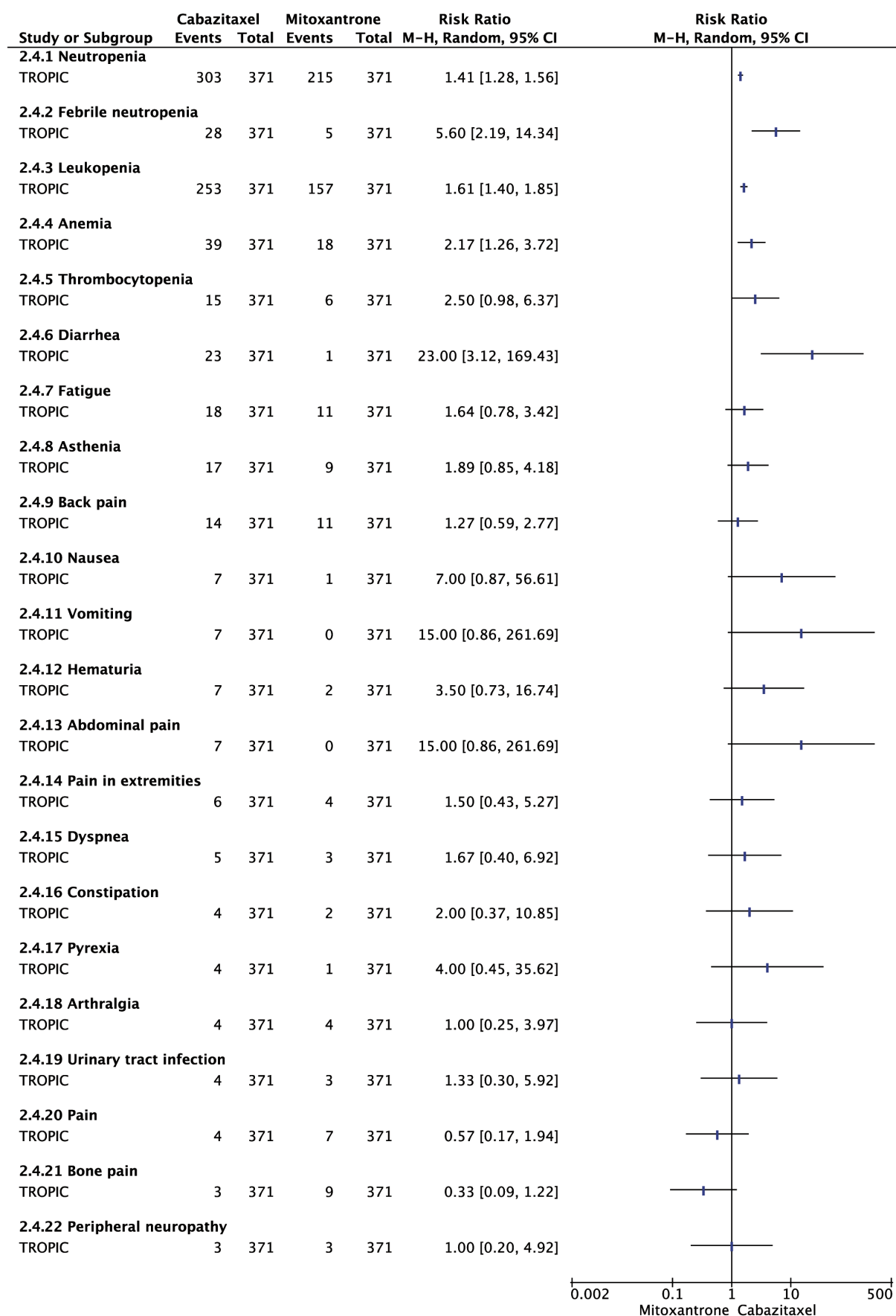
3. COU-AA-301 study
(abiraterone acetate plus prednisone versus placebo plus prednisone)



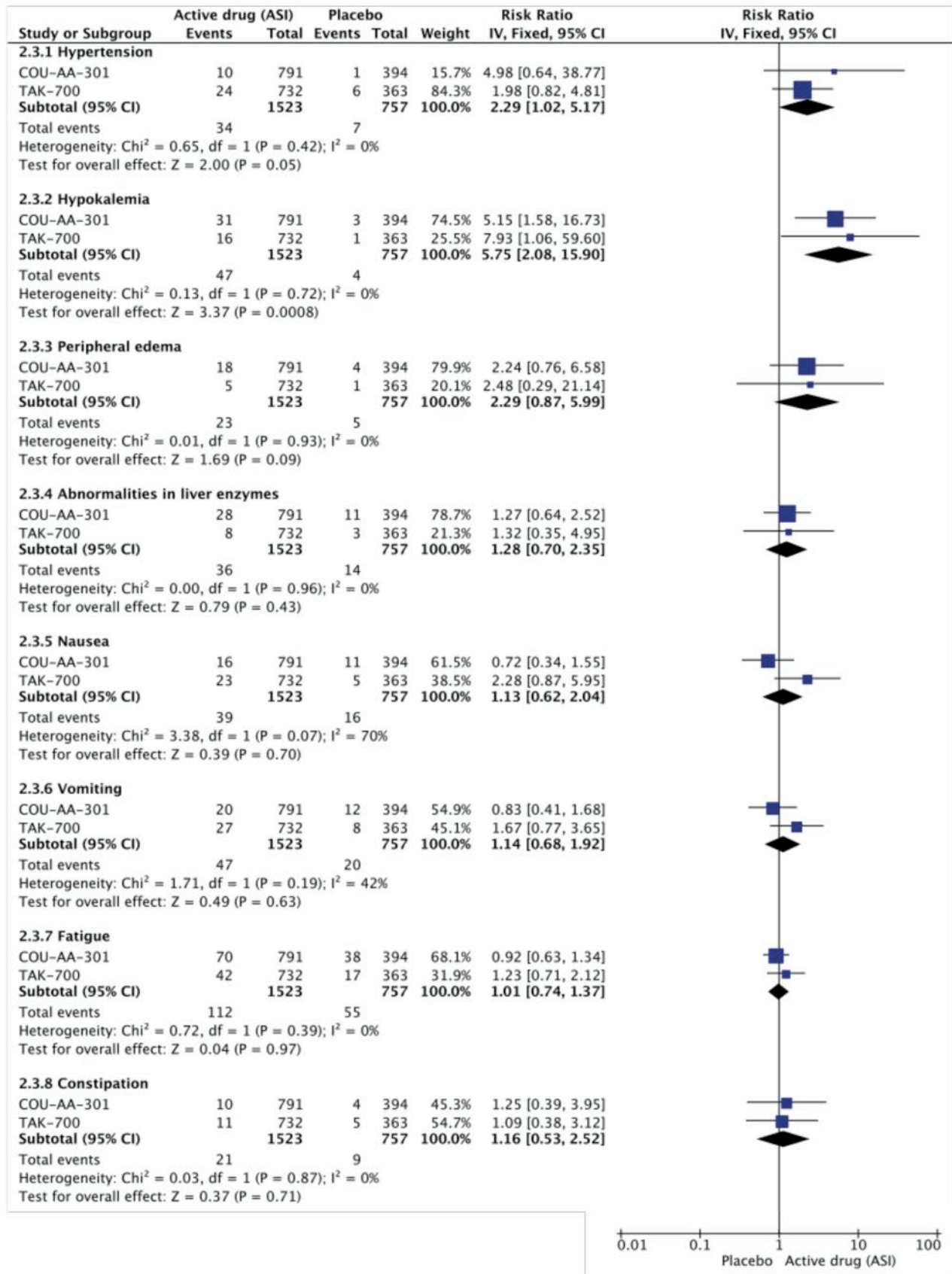
4. TAK-700 study (orteronel plus prednisone versus placebo plus prednisone)



5. TROPIC study (cabazitaxel plus prednisone versus mitoxantrone plus prednisone)



6. Androgen synthesis inhibitors (ASI) plus prednisone versus placebo plus prednisone (pooled analysis)



6. Androgen synthesis inhibitors (ASI) plus prednisone versus placebo plus prednisone (pooled analysis, continuation)

