Blank Data Extraction Form and Quality Assessment Checklists (From the Current Report)

Vitamin D Data Abstraction Form

Should this article have been previously excluded based on the exclusion criteria?

Select an Answer

- More than 20% of the population has a condition
- No outcome of interest
- Study design: Observational study of intermediate outcomes (cardiovascular and bone outcomes)
- Study design:SR/MA
- Study design other (please specify)
- Intervention: Other dietary supplements, not controlled for

Clear Response

Do you need another article to complete this form (i.e., data is reported in another article)?

- Yes (stop until the article is linked; specify reference number)
- No

Clear Response

Was this part of a trial?

We will be compiling all the studies per trial

- Yes (specify the trial name and stop)
- No Clear Response

Study Design

- ☐ RCT/CCT
- ☐ Prospective cohort
- ☐ Nested case control
- ☐ Post hoc

Population and Study Characteristics

Inclusion criteria for the study (check all that apply)

- ☐ 0-6 months
- ☐ 7 months-2 years
- ☐ 3-8 years
- ☐ 9-18 years
- ☐ 19-50 years
- ☐ 51-70 years
- ☐ ≥71 years
- ☐ Pregnant or lactating women
- ☐ Postmenopausal women
- ☐ Preterm newborns
- ☐ Healthy
- ☐ Persons with Osteopenia
- ☐ Able to participate, understand English..
- ☐ Other 1 (please specify) _____
- ☐ Other 2 (please specify) _____
- ☐ Other 3 (please specify) _____
- ☐ Other 4 (please specify) _____
- ☐ Other 5 (please specify) _____

☐ Other 6 (please specify) _____

☐ Other 7 (please specify) _____

☐ Not specified

Exclusion criteria for the study (check all that apply)

☐ Currently or previously taking vitamin d supplements (provide detail) _____

☐ Osteoporosis

☐ Other systemic bone disease (e.g., pagets)

☐ Prior fragility fracture

☐ Prior cancer

☐ Current cancer

☐ Current cardiovascular disease

☐ Hypertension

☐ Type 2 DM

☐ Pregnant

☐ Autoimmune disease

☐ Use of antihypertensives (provide details) _____

☐ Use of drugs related to bone metabolism (provide details) _____

☐ Use of medications that interfere with vitamin k (e.g., anticoagulants) (provide details) _____

☐ Consumption of dietary supplements (provide details) _____

☐ Prior cancer diagnosis (provide details) _____

☐ Prior CVD diagnosis (provide details) _____

☐ Other comobidity(ies)(provide details) _____

☐ Other 1 (specify) _____

☐ Other 2 (specify) _____

☐ Other 3 (specify) _____

☐ Other 4 (please specify) _____

☐ Other 5 (please specify) _____

☐ Other 6 (please specify) _____

☐ Other 7 (please specify) _____

☐ Not specified

Age (indicate the mean/range/SD of the control group)

☐ Mean age (indicate NR if not reported) _____

☐ Age range (indicate NR if not reported) _____

☐ Standard Deviation (if no age range was given) _____

Race/Ethnicity

☐ Non-Hispanic white (if % was given, please specify) _____

☐ Hispanic (if % was given, please specify) _____

☐ Non-Hispanic black (if % was given, please specify) _____

☐ Asian (if % was given, please specify) _____

☐ Mixed (if % was given, please specify) _____

☐ Race not specified (if % was given, please specify) _____

☐ Other_1 (specify and if % was given, please specify) _____

☐ Other_2 (specify and if % was given, please specify) _____

☐ Other_3 (specify and if % was given, please specify) _____

☐ Other_4 (specify and if % was given, please specify) _____

☐ Other_5 (specify and if % was given, please specify) _____

☐ NR (if % was given for an unknown group, please specify) _____

Countries

- ☐ Australia (specify city, if given) _____
- ☐ Canada (specify city, if given) _____
- ☐ China (specify city, if given) _____
- ☐ Finland (specify city, if given) _____
- ☐ Germany (specify city, if given) _____
- ☐ Turkey (specify city, if given) _____
- ☐ UK (specify city, if given) _____
- ☐ USA (specify city, if given) _____
- ☐ Multiple Countries
- ☐ Other (please specify) _____
- ☐ Not reported

Enrollment profile

- ☐ # Enrolled (indicate NR if not reported) _____
- ☐ % female (indicate NR if not reported) _____

Health and Nutritional status (check all that apply)

- ☐ Healthy
- ☐ Cancer in remission
- ☐ Osteopenia/Ibd
- ☐ Low birth weight/sga
- ☐ Preterm birth
- ☐ Vitamin D deficient/depleted
- ☐ Overweight/obese
- ☐ Malnourished/frailty
- ☐ Post menopausal
- ☐ Other _____
- ☐ Not Reported

Baseline vitamin D/calcium intake/level (if reported, indicate "NR" if not reported)

Interventions/exposures

- ☐ Supplemental vitamin D (none specified)
- ☐ Supplemental vitamin D2
- ☐ Supplemental vitamin D3
- ☐ Supplemental Calcium
- ☐ Vitamin D fortified food (amount per serving, amount per day)
- ☐ Serum vitamin D
- ☐ Serum vitamin D status categories (high vs. low, tertiles, quartiles, quintiles)
- ☐ Cord blood vitamin D
- ☐ Other (specify)

Sources [to be used in the arms table]:

Serum

D

D2

D3

Ca

D+Ca

D2+Ca

D3+Ca

Placebo

Arm 1/ Exposure 1	Source/ Blood level	Number of units	Units (e.g., mg, IU)	Frequency (1x, 2x)	Interval (e.g. per day)	Duration
Arm 2/ Exposure 2	Source/ Blood level	Number of units	Units (e.g., mg, IU)	Frequency (1x, 2x)	Interval (e.g. per day)	Duration
Arm 3/ Exposure 3	Source/ Blood level	Number of units	Units (e.g., mg, IU)	Frequency (1x, 2x)	Interval (e.g. per day)	Duration
Arm 4/ Exposure 4	Source/ Blood level	Number of units	Units (e.g., mg, IU)	Frequency (1x, 2x)	Interval (e.g. per day)	Duration
Arm 5/ Exposure 5	Source/Blood level	Number of units	Units (e.g., mg, IU)	Frequency (1x, 2x)	Interval (e.g. per day)	Duration

Control 1	Source	Number of units	Units (e.g., mg, IU)	Frequency (1x, 2x)	Interval (e.g. per day)	Duration
Control 2	Source	Number of units	Units (e.g., mg, IU)	Frequency (1x, 2x)	Interval (e.g. per day)	Duration

What characteristics were the controls and cases matched on?

What confounders were controlled for in analyses

- ☐ Other nutrients or dietary factors (specify) ____
- ☐ Demographics (age, sex, race/ethnicity) (specify) ____
- ☐ Anthropometrics (specify) ____
- ☐ Medical conditions (specify) ____
- ☐ Sun exposure (specify) ____
- ☐ Smoking, other lifestyle factors (specify) ____
- ☐ Other 1 (specify) ____
- ☐ Other 2 (specify) ____
- ☐ Other 3 (specify) ____
- ☐ Other 4 (specify) ____
- ☐ Other 5 (specify) ____
- ☐ Other 6 (specify) ____
- ☐ Other 7 (specify) ____

What were the comparators?

- ☐ Placebo
- ☐ Not identified
- ☐ Other vitamin d dose (specify) ____
- ☐ Other (specify) ____

Compliance with treatment? (indicate % or number or indicate "NR" for not reported, and "NA" if there was no treatment)

Dose Response (check all that apply)

- ☐ Serum vitamin D
- ☐ Cord blood vitamin D
- ☐ Other (specify) _____

Autoimmune

- ☐ Colitis/Crohns
- ☐ Lupus
- ☐ Rheumatoid Arthritis
- ☐ Type 1 diabetes
- ☐ Other (specify) _____

Cancer

- ☐ Breast cancer
- ☐ Breast density
- ☐ Prostate cancer
- ☐ Colorectal adenoma (progression)
- ☐ Aberrant crypt cells
- ☐ Pancreatic cancer
- ☐ Any cancer mortality
- ☐ Other (specify) _____

Infections/Allergy/Asthma

- ☐ Infection-related mortality (specify) _____
- ☐ Allergy (specify) _____
- ☐ Asthma (specify) _____
- ☐ Pediatric allergy (in child of woman who was subject of intervention/exposure) (specify) _____
- ☐ Infectious process (specify) _____
- ☐ Other (specify) _____

Bone Health

- ☐ Osteoporotic/fragility fx
- ☐ Bone mineral density/content
- ☐ Rickets
- ☐ Falls
- ☐ Muscle strength
- ☐ Osteoporosis
- ☐ Other (specify) _____

Cardiovascular outcomes

- ☐ Hypertension
- ☐ Cardiovascular disease
- ☐ Myocardial infarction
- ☐ Blood pressure change
- ☐ Cardiovascular disease mortality
- ☐ Other (specify) _____

Pregnancy and/or Lactating Outcomes

- ☐ Premature birth
- ☐ Low birth weight/small for gestational age
- ☐ Pre-eclampsia
- ☐ Pregnancy hypertension
- ☐ Infant mortality
- ☐ Other (specify) _____

Adverse Events

- ☐ All-cause mortality
- ☐ Cancer mortality
- ☐ Renal outcomes
- ☐ Soft tissue calcification
- ☐ Other (specify) _____

Funding

- ☐ Government
- ☐ Private foundation
- ☐ Manufacturer
- ☐ Other (specify) _____
- ☐ Unclear

Have you reference mined this article?

- ○ Yes (specify references needed to be checked) _____

No

Clear Response

Has this form been checked by a second reviewer?

Yes

No Clear Response

Comments

QUALITY of INTERVENTIONAL STUDIES

Instructions: Y=Yes; N=No; ND=No Data; NA=not applicable

Study Design

- ○ Parallel, RCT
- ○ Cross-over, RCT
- ○ Cluster, quasi-RCT
- ○ Non-randomized, but controlled trial
- ○ Before-and-after trial
- ○ Other interventional design (please explain in detail)

Clear Response

Appropriate Randomization Technique

- ○ Y
- ○ N
- ○ ND
- ○ NA

Clear Response

Allocation Concealment

- ○ Y
- ○ N
- ○ ND
- ○ NA

Clear Response

Appropriate Washout Period

- Y
- N
- ND
- NA

Clear Response

Is the Dropout Rate <20%

- Y
- N
- ND

Clear Response

Blinded Outcome Assessment

- Y
- N
- ND

Clear Response

Intention to Treat Analysis

- Y
- N
- ND
- NA

Clear Response

Appropriate Statistical Analysis

- Y
- N

- ND

Clear Response

Assessment for Confounding

- Y
- N
- ND
- NA

Clear Response

Clear Reporting with No Discrepancies

- Y
- N

Clear Response

OVERALL Grade

- A
- B (explanation for overall quality grade)
- C (explanation for overall quality grade)

Clear Response

Comments

QUALITY of COHORT OR NESTED CASE-CONTROL STUDIES

Population

a) Eligibility criteria clear?

- Y
- N

Clear Response

b) Sampling of population random or consecutive?

- Y
- N

Clear Response

Exposure (All)

a) Exposure assessor blinded to outcome info?

- Y
- N

Clear Response

b) Outcome assessor blinded to exposure measurement?

- Y
- N

Clear Response

Dietary assessment*

*Check “NA” and skip all questions if study did not use dietary assessment or biomarkers

a) Method reported?

- Y
- N
- NA

Clear Response

b) Food composition database or suppl composition reported?

- Y
- N
- NA

Clear Response

c) Internal calibration of method perform (if FFQ)?

- Y
- N
- NA

Clear Response

Biomarkers*

*Check "NA" and skip all questions if study did not use dietary assessment or biomarkers

a) One of the prespecified methods* was used?

*Prespecified methods: HPLC, RIA kits, LC-MS/MS; EIA/Chemiluminescence

- Y
- N
- NA

Clear Response

b) Time from sample collection to sample analysis reported?

- Y
- N
- NA

Clear Response

Comparator

a) Level of the exposure in comparative categories (e.g., quartiles) is given (ranges)?*

*applicable for categorical analyses only

- Y
- N

Clear Response

Statistical Analysis

a) Adjusted or matched for ANY confounders (other than age and sex)?*

*We will judge in the end if the set of confounders is adequate

- Y
- N

Clear Response

b) Justification of final adjusted model selection?

- Y
- N

Clear Response

Outcome

a) Clear definition of outcome, including time of ascertainment?

Y

N

Clear Response

b) Loss to follow-up <20%?

Y

N

Clear Response

c) Do the authors specify a primary outcome?

Y

N

NA

Clear Response

Design

a) Prospective collection of data?

Y

N

Clear Response

b) Analysis was planned when cohort was formed?

Y

N

Clear Response

c) Justification of sample size (includes sample size calculations)?

Y

N

NA

Clear Response

OVERALL Grade (A/B/C):

A

B (explanation for overall quality grade)

C (explanation for overall quality grade)

Clear Response

Comments