

Appendix
Data collection form

**Vitamin D Supplementation to Prevent Vitamin D Deficiency for Children with
Epilepsy: Randomized Pragmatic Trial Protocol**

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Baseline data form visit 1

Sex: Male Female

Age-----

Date of Birth:

City:

Educational level: Father: ----- Mother: -----

Pregnancy: Full Term Preterm

DEVELOPMENTAL HISTORY: Normal Delayed

Seizure Type:

Idiopathic Cryptogenic (cause unknown) Symptomatic
(lesion)

Treatment failure:

1-SEIZURE Control Over last 6 months :

Seizure Free: yes NO

if not seizure free over last 6 months, what is the most applicable seizure frequency:

per dayper week per month.....

2-New AED added: yes NO

3-Current AED dose increased: yes NO

Other medical diagnosis:

Medications:

CURRENT AEDs

Type	AED Name	Total Dose/day	Type	AED Name	Total Dose/day
	Carbamazepine			phenobarbitone	
	Valproic Acid			Topiramate	
	Lamotrigine			Ethosuximide	
	Levetiracetam			Clonazepam	

	Phenytoin			Clobazam	
				Vigabatrin	

Other medications:

	Start of therapy date	Dose	Indication

OTHER TREATMENT:

Ketogenic Diet: Yes No

Vagal Nerve Stimulation Yes No

Epilepsy surgery: Yes No

Vitamin D deficiency risk factors:

1. Family member with vitamin D deficiency Yes No

2. Previous treatment for vitamin D deficiency Yes No

3. Outdoor time (Hr/day).....

4. Screen time (Hr/day).....

5. Self-reported sun exposure time (Hr/day).....

6. Physical activity min/day (Hr/day).....

7. Nutritional intake: food frequency questionnaire

CLINICAL EXAMINATION

Weight: _____kg Height: _____cm

BMI=.....Kg/m² BMI z-score:.....

Rickets signs: Yes No

If yes specify which signs:

Bowing of long bones Yes No

Wide wrist jointYes No

Rackitic rosery Yes No

Harrison sulcus Yes No

Craniotabes Yes No

INVESTIGATIONS:

Test name	Level	N, L, H	Action required	Issue cleared
CBC: WBC				
HB				
PLT				
Total ca				
Albumin				
Corrected ca				
AST				
ALT				
GGT				
ALP				
25 hydroxy Vitamin D level				
PTH				
TSH				
FT4				
Urine Ca/creatinine ratio				
PH				
Co2				
HCO3				
BUN				
Creatinin				
Celiac screening				
Bone mineral density				
Total body Z-score				
Spine body Z-score				
Femoral neck body Z-score				
Fracture rate last 6 months				

**Vitamin D Supplementation to Prevent Vitamin D Deficiency for Children with
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Post-treatment data form visit 2

Treatment course number

Treatment failure Over the last **2 months** :

SEIZURE Control

Seizure Free: yes NO

if not seizure free over last **2 months**, what is the most applicable seizure frequency:

per day per week per month.....

2-New AED added: yes NO

3- Current ADE dose increased: yes NO

CURRENT AEDs

Type	AED Name	Total Dose/day	Type	AED Name	Total Dose/day
	Carbamazepine			phenobarbitone	
	Valproic Acid			Topiramate	
	Lamotrigine			Ethosuximide	
	Levetiracetam			Clonazepam	
	Phenytoin			Clobazam	
				Vigabatin	

Other medications:

	Start of therapy date	Dose	Indication

OTHER TREATMENT:

Ketogenic Diet: Yes No
 Vagal Nerve Stimulation Yes No
 Epilepsy surgery: Yes No

Vitamin D deficiency risk factors:

1. Family member with vitamin D deficiency Yes No
2. Previous treatment for vitamin D deficiency Yes No
3. Outdoor time (Hr/day).....
4. Screen time (Hr/day).....
5. Self-reported sun exposure time (Hr/day).....
6. Physical activity min/day (Hr/day).....

CLINICAL EXAMINATION

Weight: _____kg Height: _____cm
 BMI=.....Kg/m² BMI z-score:.....

Rickets signs: Yes No

If yes specify which signs:

- Bowing of long bones Yes No
 Wide wrist jointYes No
 Rackitic rosery Yes No
 Harrison sulcusYes No
 Craniotabes Yes No

INVESTIGATIONS:

Test name	Level	N, L, H	Action required	Issue cleared
Total Calcium				
ALP				
Corrected Calcium				
PTH				

Urine Ca/creatinine ratio				
25 (OH) vitamin D Level				

**Vitamin D Supplementation to Prevent Vitamin D Deficiency for Children with
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Mid-study follow up data form visit 4**

INVESTIGATIONS:

Test name	Level	N, L, H	Action required	Issue cleared
Total ca				
ALP				
Corrected Ca				
PTH				
Urine Ca/creatinine ratio				
25 (OH) vitamin D Level 3 months after prophylaxis				

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End of study data form visit 5

Treatment failure Over the last **6 months** :

SEIZURE Control

Seizure Free: yes NO

if not seizure free over last **6 months**, what is the most applicable seizure frequency:

per day per week per month.....

2-New AED added: yes NO

3-Current ADE dose increased: yes NO

CURRENT AEDs

Type	AED Name	Total Dose/day	Type	AED Name	Total Dose/day
	Carbamazepine			phenobarbitone	
	Valproic Acid			Topiramate	
	Lamotrigine			Ethosuximide	
	Levetiracetam			Clonazepam	
	Phenytoin			Clobazam	
				Vigabatrin	

Other medications:

	Start of therapy date	Dose	Indication

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OTHER TREATMENT:

- Ketogenic Diet: Yes No
- Vagal Nerve Stimulation Yes No
- Epilepsy surgery: Yes No

Vitamin D deficiency risk factors:

1. Family member with vitamin D deficiency Yes No
2. Previous treatment for vitamin D deficiency Yes No
3. Outdoor time (Hr/day).....
4. Screen time (Hr/day).....
5. Self-reported sun exposure time (Hr/day).....
6. Physical activity min/day (Hr/day).....

CLINICAL EXAMINATION

Weight: _____kg Height: _____cm

BMI=.....Kg/m² BMI z-score:.....

Rickets signs: Yes No

If yes specify which signs:

- Bowing of long bones Yes No
- Wide wrist jointYes No
- Rackitic rosery Yes No
- Harrison sulcusYes No
- Craniotabes Yes No

INVESTIGATIONS:

Test name	Level	N, L, H	Action required	Issue cleared
Total ca				
ALP				
Corrected Ca				
PTH				
Urine Ca/creatinine ratio				

25 (OH) vitamin D Level 6 months after prophylaxis				
Bone mineral density				
Total body Z-score				
Spine body Z-score				
Femoral neck body Z- score				
Fracture rate last 6 months				

Abbreviations:

N, L, H : Normal,Low,High

AED: Antiepileptic Drug

BMI: Body Mass Index

PTH: Parathyroid Hormone

BMD: Bone Mineral Density

25 OH Vitamin D: 25-Hydroxy Vitamin D

CBC: Complete Blood Count

WBC: White Blood Cell

HB: Hemoglobin

PLT: Platelet

Ca: Calcium

AST: Aspartate aminotransferase

ALT: Alanine transaminase

GGT: Gamma-glutamyl transferase

ALP: Alkaline Phosphatase

TSH: Thyroid Stimulating Hormone

FT4: Free thyroxine

Co2: Carbon dioxide

HCO3: Bicarbonate

BUN: Blood urea nitrogen